



## **PSJ2 Exh 170**

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## Situation Analysis

June 2012



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## Situation Analysis Content



- Market Dynamics
- Performance Overview
- EXALGO® Profile
- Managed Care Analysis
- HCP Prescribing Behavior
- Patient Behavior
- Sales Force Execution
- Financial Information
- 32mg Launch

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## Executive Summary – Slide 1



- Although the pain market generates almost 400 Million TRx's annually, EXALGO® competes with a small number of other high-end, branded, powerful Step 3 extended release products, which in total comprise just a few million TRx's.
- The competitive products belong to large companies that dedicate more sales representatives and promotional dollars to this class; in addition, new products are scheduled to launch in the near term.
- Despite this competition, EXALGO® has excelled, more than doubling TRx volume annually during the first two year's of its launch.
- Over 8,000 prescribers have written at least one EXALGO® TRx since launch: because a small group of Pain Specialists typically prescribe this and competitive products, 88% of EXALGO® volume is driven by the top 2,276 EXALGO® prescribers.
- Sales representatives have exercised their discretion in following the call plan, spending more time with high volume prescribers and less time with others.
- Indeed, the highest decile, Tier A, Priority EP prescribers received up to 40 calls in just 26 weeks, while the "True Zero" prescribers averaged less than 1 per month.
- Unfortunately, because the sales representatives devoted extra time to high volume prescribers, month to month many of the low volume, Tier A prescribers were ignored

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## Executive Summary – Slide 2



- Even so, about 70% of targeted HCPs have not prescribed EXALGO® in the last year, despite receiving 43% of all calls.
- Patients care most about clinical efficacy, while HCP selects products based on specific attributes including insurance coverage, number of available dosage strengths, efficacy across types of pain and efficacy of the molecule.
- In general, HCP's view EXALGO® as similar to other potent ER opioids, except that the product has less dosing options and worse formulary status.
- EXALGO® is more often used later in line of therapy than Opana ER, and EXALGO® patients are less persistent than Opana ER patients and are prescribed significantly lower daily doses.
- Managed care access...
- The 32mg launch provides an opportunity to reach the 44% of prescriptions that are not covered by the current EXALGO® strengths and to fend off generic encroachment by Abbott Laboratories

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## Market Dynamics



- Overview
- Competitive Landscape
- Patient Dynamics
- HCP Perceptions

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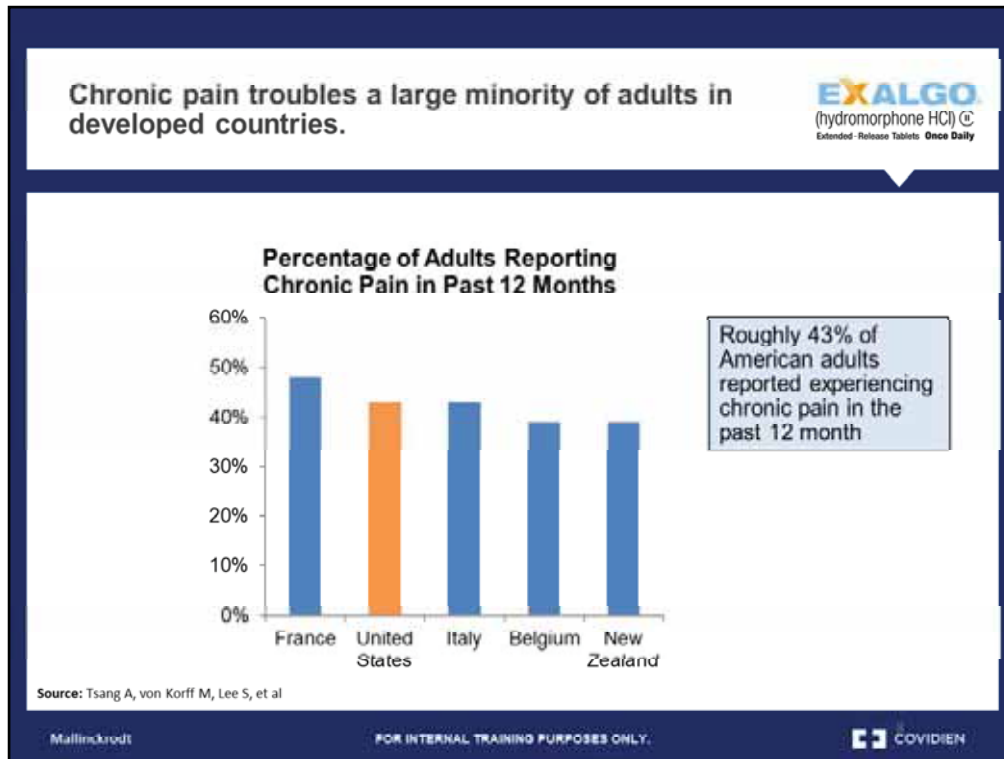
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## Market Overview Summary



- Chronic pain troubles a large minority of adults in developed countries, including over 40% of American adults.
- Because so many Americans suffer from pain, this therapeutic class totaled a remarkable 377 Million TRx's and over \$11 Billion in sales during fiscal year 2012.
- The World Health Organization has defined a "pain ladder" and articulated the recommended therapy for each step, from non-opioids to strong opioids.
- The Step 3 market, which includes the most potent opioids, should remain stable with slightly diminishing year-on-year growth for at least the next five years.
- The Step 3 market represents only a small portion of the overall market (12.5%) and can be further sub-divided into Immediate Release (IR) and Extended Release (ER) and between branded products and generics.
- Out of the entire market, EXALGO® competes with a small number of high-end opioids for about 2 million Step ER branded prescriptions (excluding Oxycontin).



- Chronic pain is a worldwide problem. The prevalence of chronic pain in developed countries ranges from 27% to 48%,<sup>2</sup> and has been estimated to be 43% in the United States.<sup>2</sup>
- In a World Health Organization study of chronic pain, 22% of primary care patients reported persistent pain, and patients with pain were more likely to have an anxiety or depressive disorder, have unfavorable health perceptions, and experience significant activity limitations.<sup>3</sup>

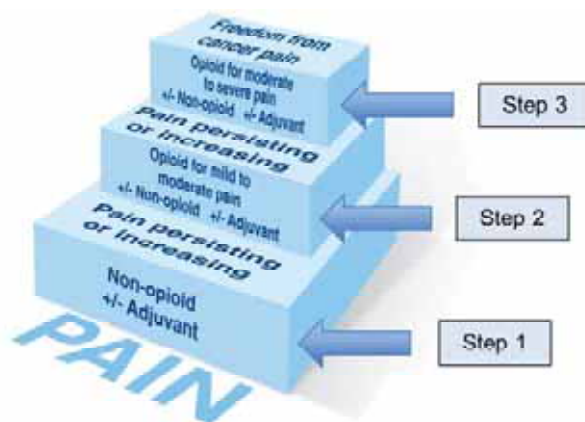
#### References

2. Tsang A, von Korff M, Lee S, et al. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. *J Pain*. 2008;9(10):883-891.
3. Gureje O, von Korff M, Simon GE, Gater R. Persistent pain and well-being: a World Health Organization Study in primary care. *JAMA*. 1998;280(2):147-151.

The World Health Organization has defined a "pain ladder" and articulated the *recommended therapy* for each step, from non-opioid to strong opioid.

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### WHO Pain Ladder



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Because so many Americans suffer from pain, this therapeutic class will generate 377 Million TRx's and over \$11 Billion in sales during fiscal year 2012.

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**Pain Therapeutic Area FY12**  
\$11.3B in Sales, 377 MMM TRx's



Step	\$ Sales Billions	CAGR – '12-'17	TRx Millions	CAGR – '12-'17
3	6.6	4%	47	4%
2	1.7	18%	228	3%
1	3.0	-5%	102	4%

Sources: IMS NSP & NPA ending September 30, 2011; internal market projections.

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The Step 3 products represent just 12.5% of the total TRx volume (47 / 377 Million) but an astonishing 58% of the revenue (\$6.6 / \$11.3 Billion).

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**Pain Therapeutic Area FY12**  
\$11.3B in Sales, 377 MMM TRx's

Step 3 products: 12.5 %  
of the TRx volume (47 /  
47 + 228 + 102 Million)

Step 3 products: 58% of  
the total revenue (6.6 / 6.6  
+ 1.7 + 3.0 Billion)

Step	\$ Sales Billion	CAGR – '12-'17	TRx Millions	CAGR – '12-'17
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1	3.0	-5%	102	4%

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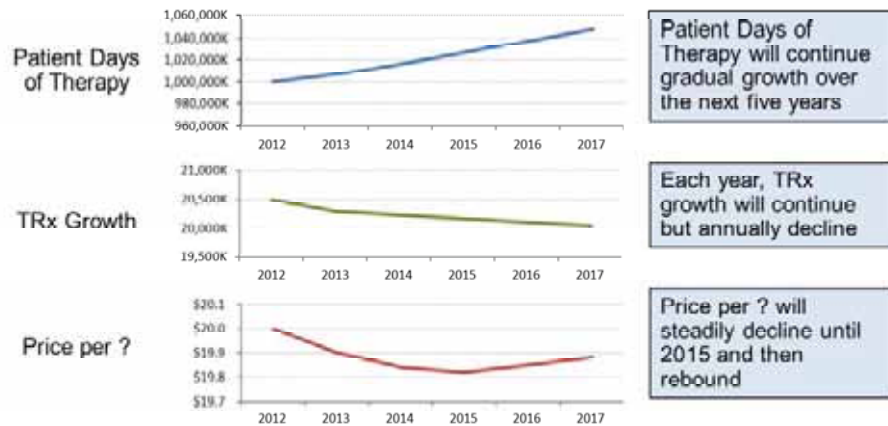
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The Step 3 Opioid market volume should remain stable for the next five years, although generic entrants will place meaningful pressure on pricing.

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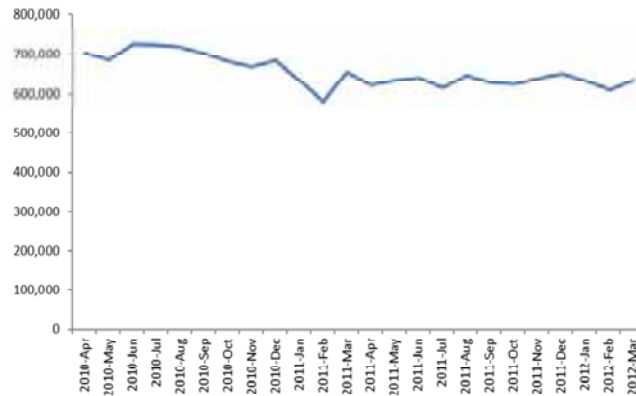
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During the last 24 months (ending March, 2012), the market surprisingly contracted about 7% year on year.

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### EXALGO® Market TRx



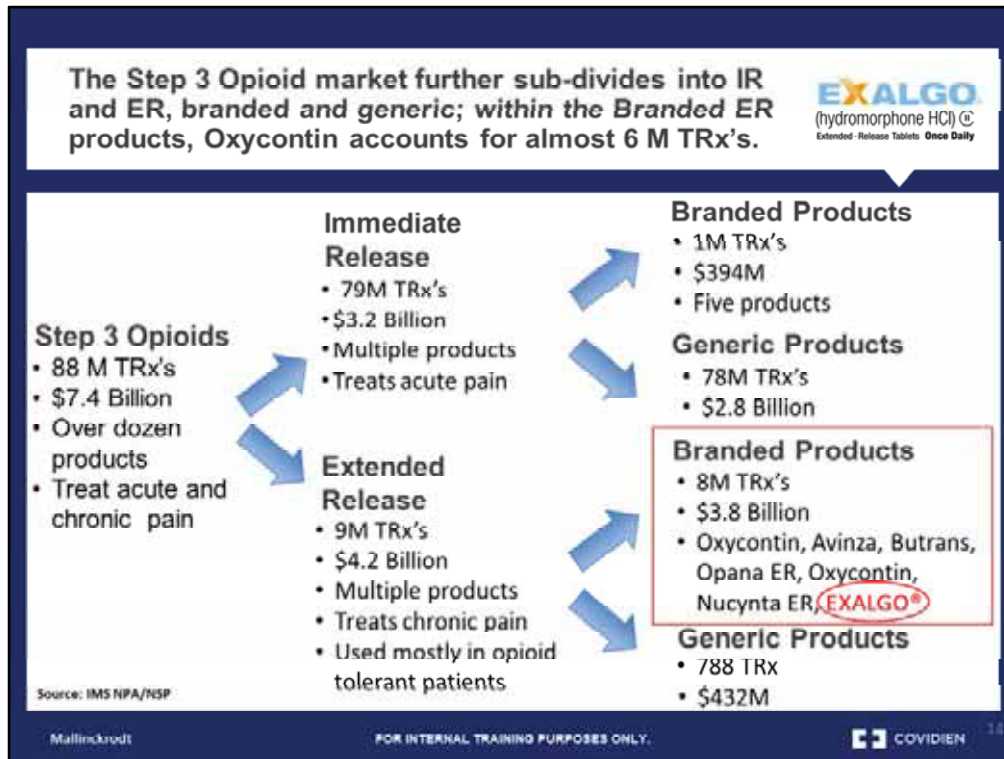
Source: IMS Xponent® PlanTrak™ Monthly data, from April 2010 through March 2012.

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## Market Dynamics



- Overview
- Competitive Landscape
- Patient Dynamics
- HCP Perceptions

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## Competitive Landscape Summary



- Of the five major branded Step 3 competitors, Oxycontin has dominated the landscape for years, enjoying better than 75% market share; a reformulation, launched over a year ago, led to questions about the product efficacy and share loss.
- Opana ER has grown steadily since its launch three years ago and enjoys the next highest share, achieving 15% in 2011.
- Nucynta ER and Butrans are later entrants, each striving to carve out their niche: Nucynta ER has discounted heavily and won formulary positions, while Butrans has pitched great efficacy with a 7 day patch.
- These competitors describe their target patient similarly: middle aged, employed or recently retired, suffering from chronic pain, and on other medication unsuccessfully.
- Nucynta ER has over 1,000 representatives detailing the product, and all of the competitive companies support a larger sales force than Covidien's.
- Because the Step 3 market is not yet genericized, competitive companies plan multiple launches into this therapeutic space during the next three years.

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The current Step 3 ER market basket includes five competing products.

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<u>Product</u>	<u>Company</u>	<u>Peak Sales</u>	<u>2011 TRx Volume</u>	<u>2011 TRx Share</u>
Oxycontin	Purdue	\$3,088 MM (2010)	6.48 MM	77%
Opana ER	Endo	\$635 MM (2011)	1.24 MM	15%
Avinza	King	\$175 MM (2005)	0.30 MM	4%
Butrans	Purdue	\$57 MM (2011)	0.28 MM	3%
Nucynta ER	JNJ	\$15 MM (2011)	0.38 MM	.5%
EXALGO®	Covidien	\$75 MM (2011)	0.99 MM	1%

Source: ???

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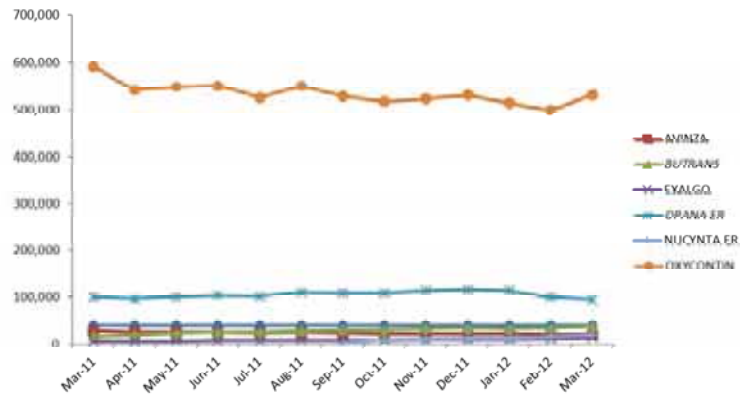
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Oxycontin, the clear market leader, has lost volume over the last 12 months. following the launch of a reformulation (designed to deter abuse).

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EXALGO® Market Basket TRx



Source: IMS NPA

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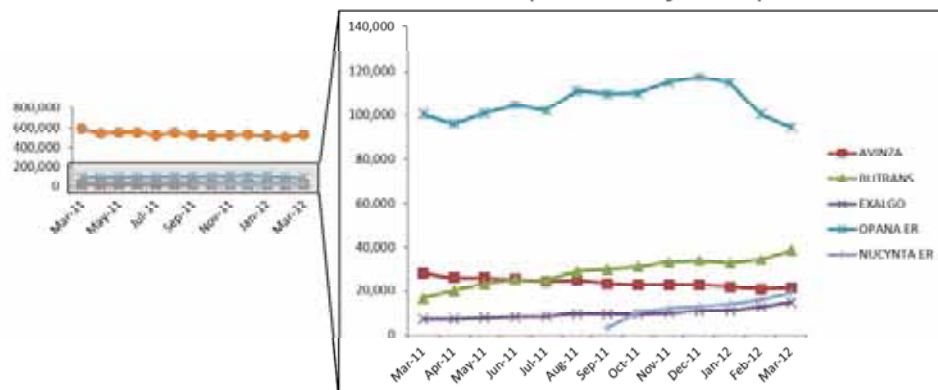
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Among the smaller volume branded products, Opana ER enjoys the highest TRx volume, despite a recent manufacturing concern.

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### EXALGO® Market Basket TRx (without OxyContin)



Source: IMS NPA

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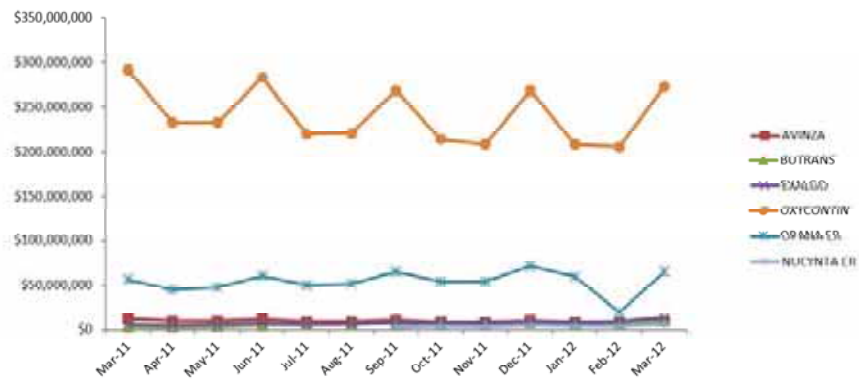
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Oxycontin contributes roughly \$250 million on average to the market each month, dwarfing the other brands.

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### EXALGO® Market Basket Dollars



Source: IMS NSP

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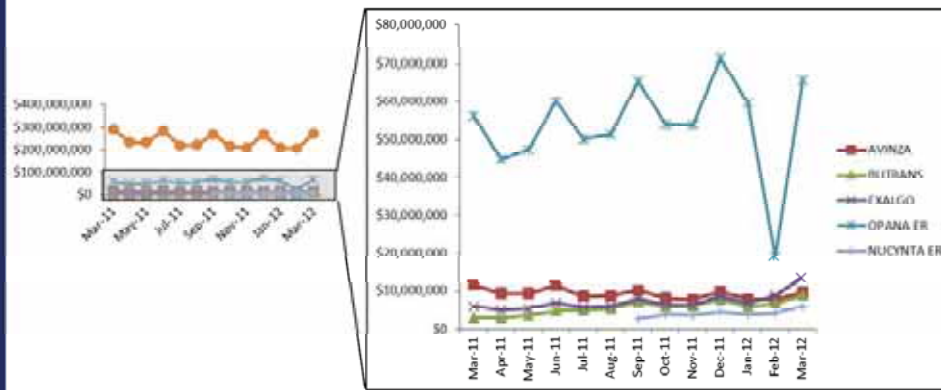
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**EXALGO® increased sales from February to March 2012 by \$4.5 million.**

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**EXALGO® Market Basket Dollars (without OxyContin)**



Source: IMS NSP

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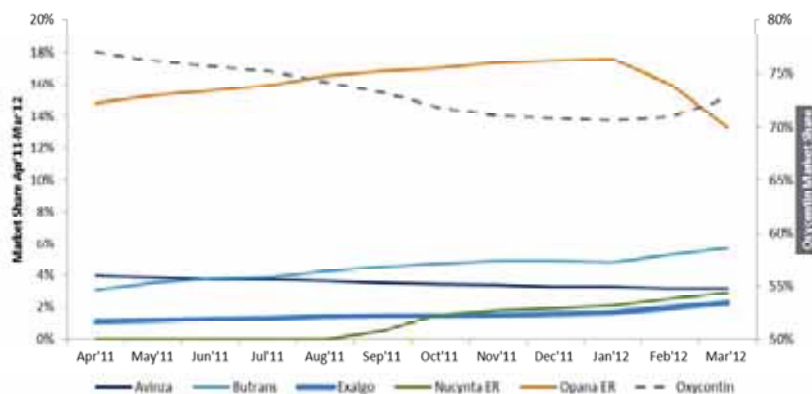
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**Overall OxyContin, Opana ER and Avinza lost share, while EXALGO®, Butrans and Nucynta ER gained share.**

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### ER Market Share Breakout – All Prescribers



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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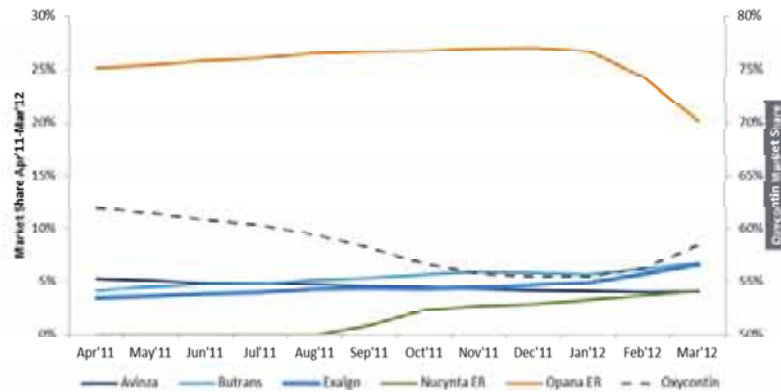
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Among just EXALGO® writers, OxyContin still captures 70% or more of the Step 3 market volume.

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### ER Market Share Breakout of EXALGO® Writers



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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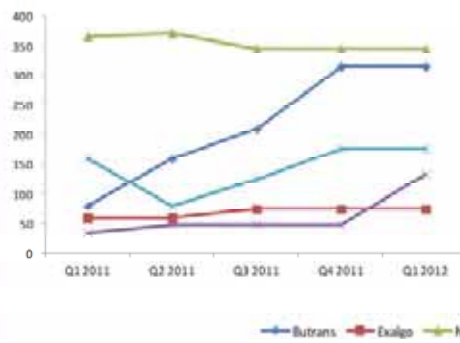
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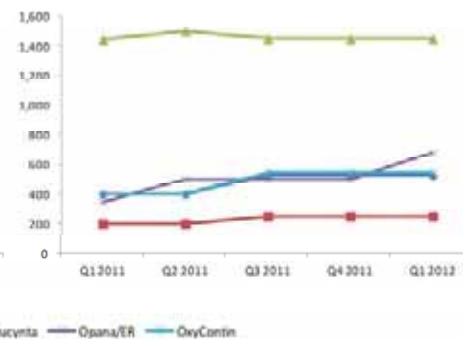
The competing companies devote more estimated sales force resources to their Step 3 pain products than Covidien (Avinza is no longer promoted).

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**Mkt Basket Sales Force FTE Count**



**Mkt Basket Sales Force Total Rep Count**



Source: SFSS

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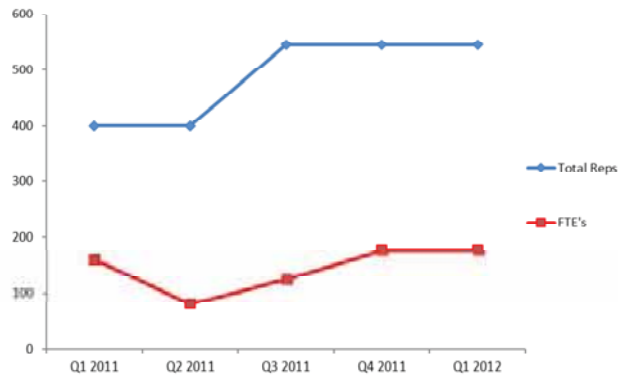
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To support the Butrans Launch in Q2 2011, 80 FTE's (½ the total) were moved off of OxyContin; to support both brands, Purdue hired an additional 150 reps.

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OxyContin Rep Count (SFSS)



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An OxyContin patient is described as a retired,  
middle aged male, recovering from a back operation.

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#### OxyContin Patient Profile



**Demographic:** Middle age male

**Condition:** Recovering from a back operation

**Occupation:** Retired

**Medication:** Currently on 20mg on OxyContin and 2 supplemental IR opioids but the pain persists

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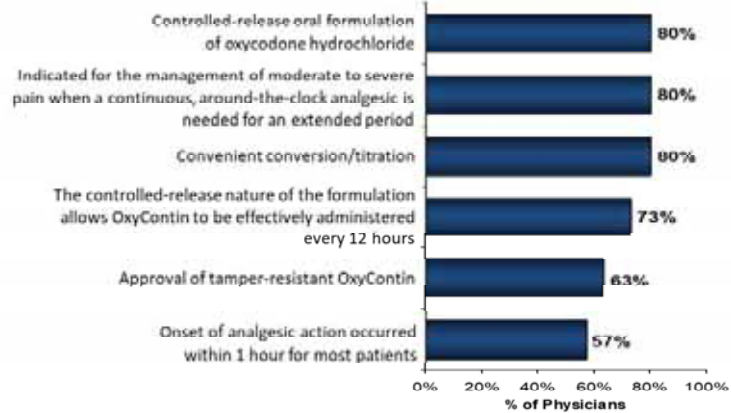
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**Eighty percent of physicians recalled the top three OxyContin messages: controlled release, continuous analgesic and convenient conversion.**



### Top OxyContin Messages



Source: Message Recall Wave 3.

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Despite favorable positioning, a specialty sales force, and a robust track record, *OxyContin* faces patent expiry in the next year.



### OxyContin SWOT

#### Strengths

- Best managed care position/script pass-through in space
- Favorable price position relative to ER brands
- Best product awareness in category
- Dedicated pain specialty sales force
- Multiple dose options aligns with a primary need in the ER pain category
- Broad range of use

#### Weaknesses

- Looming patent loss in 4/2013
- Market did not widely accept TR reformulation

#### Opportunities

- Expanding awareness of the ER pain category

#### Threats

- Increased scrutiny of OxyContin
- Increased scrutiny of the ER pain category
- 3 new brands enter space over the past 3 year period
- Continued expansion of ER opioid generic availability

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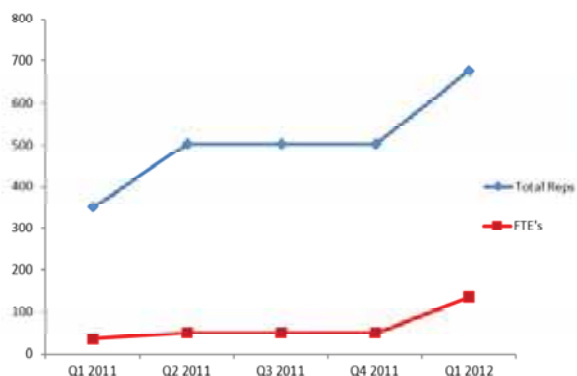
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In Q1 2012, Endo folded its "General Pharma" sales force and established a "Specialty Pain" sales force.

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Opana ER Rep Count (SFSS)



Endo added 175 total representatives and 85 Opana FTEs.

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An Opana ER patient is characterized as a working male in his early 50's who suffered a back injury more than a year ago.

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#### Opana ER Patient Profile



**Demographic:** 53 year old male  
**Condition:** Back injury >1 year ago  
**Occupation:** Construction-Breadwinner  
**Medication:** Q12 hr ER opioid & 4 doses of IR for breakthrough pain

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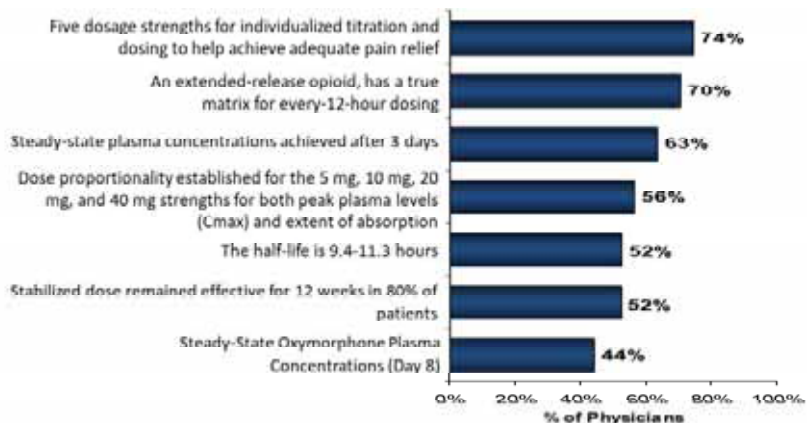
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The top two Opana ER messages focused on titration and dosing.

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### Top Opana ER Messages



Source: Message Recall Wave 3.

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**Opana ER faced supply disruption due to a plant shutdown in Q1 2012.**

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### Opana ER SWOT

#### Strengths

- Strong patent position
- Dedicated pain specialty sales force
- Multiple dose options aligns with a primary need in the ER pain category
- Sales align to tactics
- Broad range of use
- TR reformulation aligns with stated attribute

#### Weaknesses

#### Opportunities

- Expanding awareness of the ER pain category
- Increased scrutiny of Oxycontin positions Opana to move up in the algorithm

#### Threats

- Continued expansion of non-TR opana generic availability
- Continued expansion of ER opioid generics
- Increased scrutiny of the ER pain category
- Q1 2012 inability to supply market due to plant shutdown

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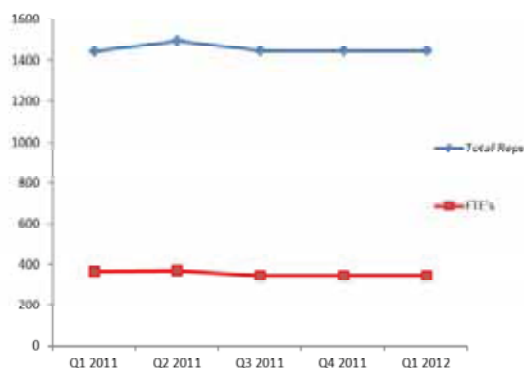
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**Nucynta(ER) is the most heavily promoted product in the Step 2 and 3 markets with 350 FTEs and over 1,400 total reps.**

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**Nucynta ER Rep Count (SFSS)**



Sales Force levels have remained steady for the last year.

Nucynta(ER)'s total number of reps is second only to Vimovo in the pain space.

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**Nucynta ER patients are described as working middle aged males who suffer from Chronic lower back pain.**

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#### Nucynta ER Patient Profile



**Demographic:** Middle aged male  
**Condition:** Chronic lower back pain  
**Occupation:** Employed  
**Medication:** Multiple IR opioids

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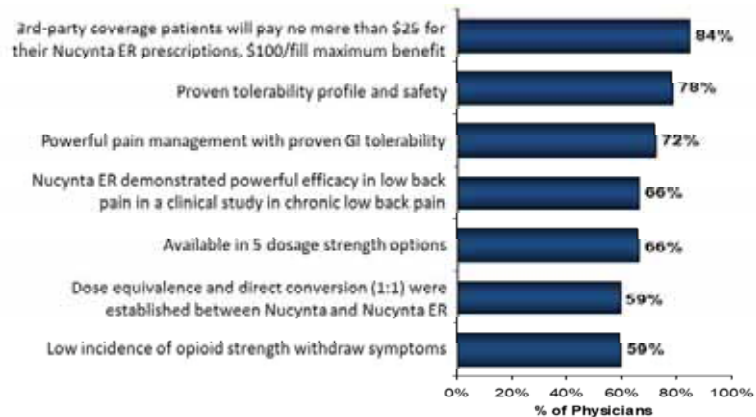
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**The top Nucynta ER message focused on insurance coverage, followed by messaging on tolerability and safety.**

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### Top Nucynta ER Messages



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**The Nucynta ER pricing is the most competitive in the ER category, and the brand faces fewer weaknesses and threats than other competitors.**



### Nucynta ER SWOT

#### Strengths

- Managed care position/script pass-through already at parity to Opana
- Most competitive price position in ER category
- Largest sales force in ER pain space
- Multiple dose options aligns with a primary need in the ER pain category

#### Weaknesses

#### Opportunities

- Expanding awareness of the ER pain category
- Market interest in trialing none Oxy offerings

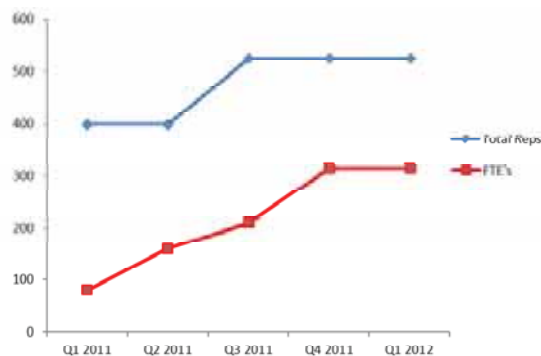
#### Threats

- Continued expansion of ER opioid generic availability
- Increased scrutiny of ER opioid category

In Q2 2011, Purdue moved 80 FTEs from OxyContin to Butrans.

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Butrans Rep Count (SFSS)



An additional 50 and 105 FTEs were added in Q3 and Q4, respectively.

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**Butrans targets middle aged female patients who are active retirees with Chronic OA pain.**

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### Butrans Patient Profile



**Demographic:** Middle-aged female  
**Condition:** Chronic OA pain  
**Occupation:** Retired but active  
**Medication:** NSAIDs and IR opioids for breakthrough pain

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**Butrans<sup>®</sup> messaging focuses on OA pain relief and the seven day release cycle.**

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#### **Butrans Messages**

- One Butrans - 7 days of buprenorphine delivery
- Butrans Transdermal System is an analgesic product that delivers continuous release of medication for seven days
- Butrans Trial Offer: covers patients co-pay for up to \$75 on their first 28-day prescription
- Butrans Savings Card for savings of up to \$40 on each prescription
- When suffering moderate OA pain, Butrans patch may help make everyday tasks more manageable again
- Prescribe your patients Butrans patch for continuous relief from OA

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While Butrans enjoys extensive experience in the pain category and a dedicated specialty sales force, its patch delivery poses some potential weaknesses.

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#### Butrans SWOT

##### Strengths

- Dedicated pain specialty sales force
- Backed by extensive experience in the pain category

##### Weaknesses

- Weak strength offering relative to product set
- Patch delivery not a broad need in ER space

##### Opportunities

- Expanding awareness of the ER pain category

##### Threats

- Increased scrutiny of the ER pain category
- Continued expansion of ER opioid generic availability

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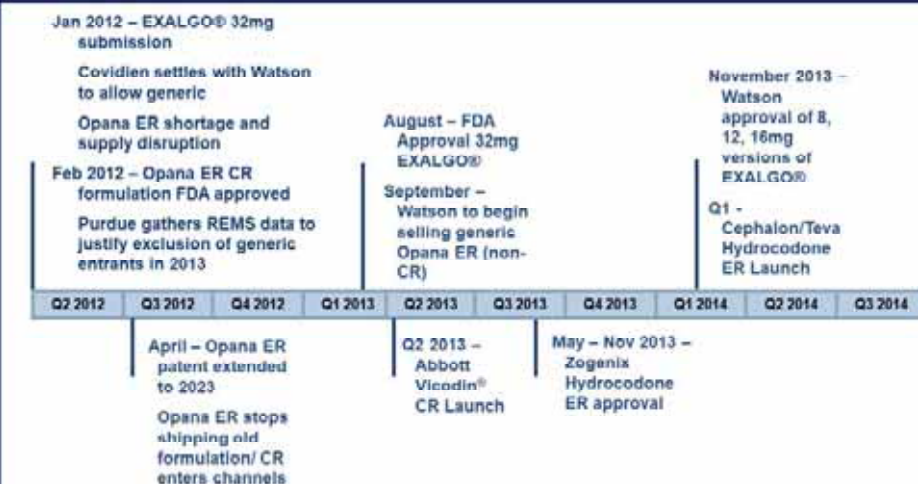
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During the next two years, multiple companies will impact the market through new product launches, new formulations, and generic entrants.

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Source: ???

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## Market Dynamics

- Overview
- Competitive Landscape
- Patient Dynamics
- HCP Perceptions



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## Patient Dynamics Summary



- Like patients taking medications in many therapeutic areas, these patients must navigate the entire process, from first visiting a clinician to ultimately filling their prescription at the pharmacy.
- These patients, however, have previously tried and failed multiple other products and suffer complex lives due to persistent, chronic pain.
- Patients report that they prefer products that work well: clinical efficacy ranks as their highest priority.
- These patients, racked by pain for many years, claim that insurance status, co-pay amounts, and other non-clinical factors matter little to them.

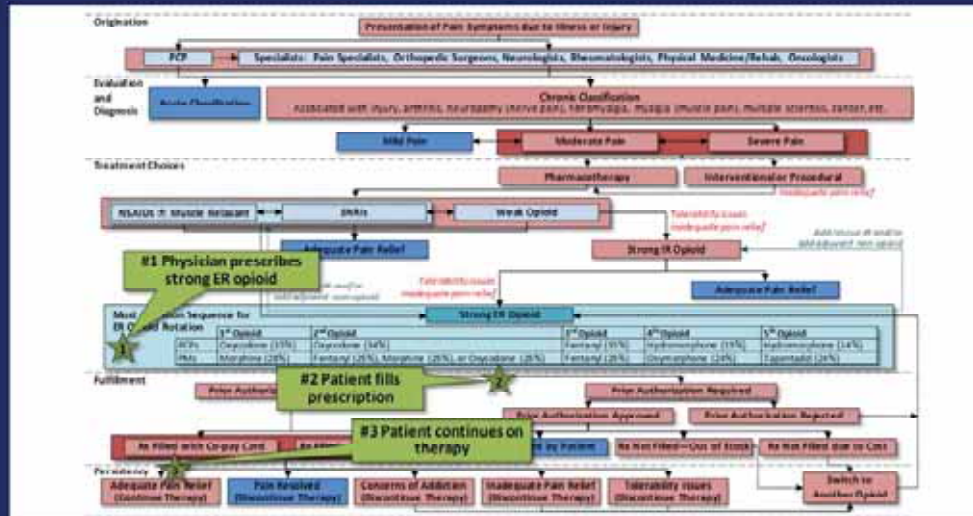
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Patients with moderate to severe pain may proceed through a complex journey before achieving adequate pharmacologic pain relief.

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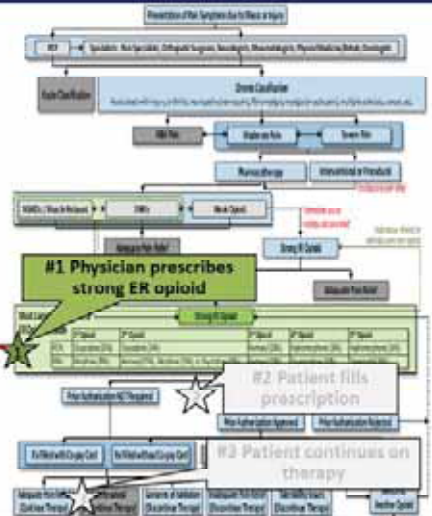
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Ideally, prescribers will select EXALGO® as their strong ER Opioid choice.

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#### Healthcare Provider Desired Behaviors

- Keep EXALGO® top of mind for HCPs
- Use EXALGO® for "high-dose" patients
- Use EXALGO® earlier in the ER opioid rotation
- Feel comfortable with the process for initiating and titrating EXALGO®
- Initiate patients on an efficacious dose of EXALGO®
- Educate patients on what to expect and set up appropriate follow-up
- Understand that EXALGO® co-pay assistance program puts patient out-of-pocket (OOP) expenses in line with other ER opioid options
- Inform patients of the EXALGO® co-pay program



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And the pharmacy and patient decisions will lead to **successfully filled prescriptions from compliant patients.**

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#### Pharmacy Desired Behaviors

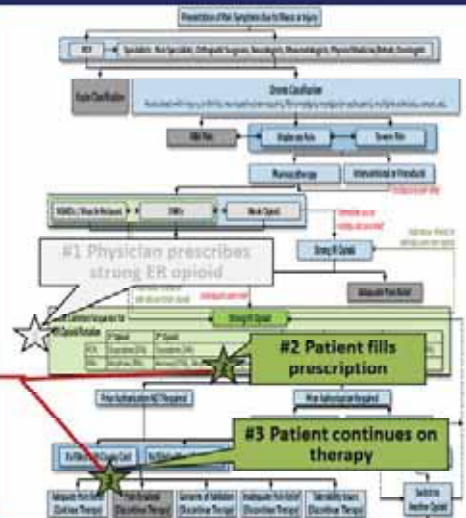
- Understand the EXALGO® co-pay program and inform patients
- Inform patients how to appropriately use EXALGO® and the time required to reach steady-state

#### Patient Desired Behaviors

- Utilize co-pay program during fulfillment

#### HCP Desired Behaviors

- Be prepared to address patient tolerability or effectiveness concerns
- Be willing to re-examine titration schedule before considering switch to an alternative ER opioid



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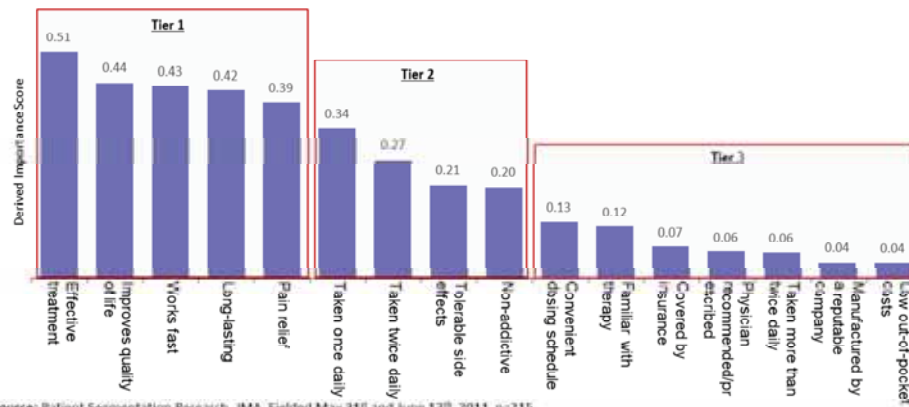
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These patients, suffering from chronic moderate to severe pain, list clinical attributes as Tier 1 in stated importance.

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### Derived Importance Score of Product Attributes

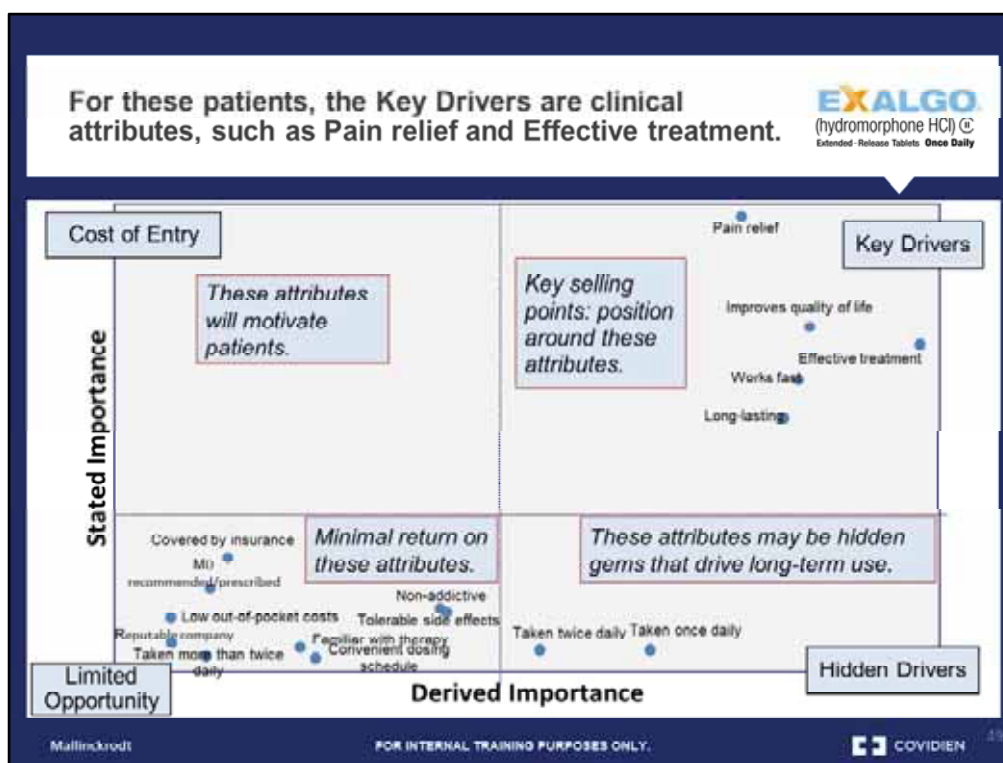


Source: Patient Segmentation Research, IMA, Fielded May 31<sup>st</sup> and June 13<sup>th</sup>, 2011, n=215

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## Market Dynamics

- Overview
- Competitive Landscape
- Patient Dynamics
- HCP Perceptions

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## HCP Perceptions Summary

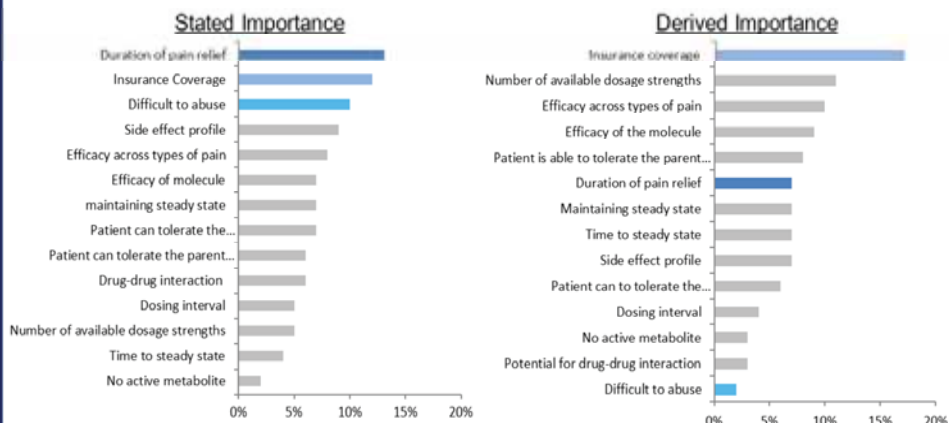


- Physicians differ with their patients in how they rank important product attributes.
- While patients focus predominantly on clinical efficacy, physicians intermingle the duration of pain relief with insurance coverage and abuse potential as top attributes.
- In a recent market research study, insurance coverage ranked as the most important attribute based on the derived importance.
- Pain specialists, who treat many of these patients, typically rely on Hydromorphones as 4<sup>th</sup> and 5<sup>th</sup> line therapy.
- Although pain specialists delay the use of Hydromorphones, they do incorporate the products in their arsenal of weapons; primary care physicians are less likely to prescribe Hydromorphones at all.

Physicians say duration of pain relief, insurance coverage, and difficult to abuse are among the top attributes.

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### ER Attribute Importance



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Pain Specialists currently reserve the use of hydromorphone as 4<sup>th</sup> or 5<sup>th</sup> agent.

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### Pain Specialist (PMs) Opioid Preference by Line of Therapy

	1 <sup>st</sup> line	2 <sup>nd</sup> line	3 <sup>rd</sup> line	4 <sup>th</sup> line	5 <sup>th</sup> line
Most Commonly Used:	Morphine (40%)	Morphine (28%)	Fentanyl (29%)	Oxycodone (23%)	Hydromorphone (20%)
2 <sup>nd</sup> Most Commonly Used:	Oxycodone (15%)	Fentanyl (20%)	Oxycodone (18%)	Buprenorphine (15%)	Tapentadol (18%)
3 <sup>rd</sup> Most Commonly Used:	Buprenorphine (12%)	Oxycodone (19%)	Tapentadol (10%)	Hydromorphone (14%)	Fentanyl (11%)
4 <sup>th</sup> Most Commonly Used:	Hydromorphone (9%)	Oxycodone (14%)	Oxycodone (14%)	Fentanyl (11%)	Buprenorphine (10%)
5 <sup>th</sup> Most Commonly Used:	Oxycodone (9%)	Tapentadol (9%)	Hydromorphone (10%)	Morphine (11%)	Oxycodone (9%)
Source: ATU Wave 3			Don't use this many opioids (0%)	Don't use this many opioids (10%)	Don't use this many opioids (21%)

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PCPs are less likely to incorporate hydromorphone in the opioid rotation.

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### Primary Care (PCPs) Opioid Preference by Line of Therapy

	1 <sup>st</sup> line	2 <sup>nd</sup> line	3 <sup>rd</sup> line	4 <sup>th</sup> line	5 <sup>th</sup> line
Most Commonly Used:	Oxycodone (42%)	Fentanyl (28%)	Fentanyl (28%)	Oxymorphone (19%)	Tapentadol (13%)
2 <sup>nd</sup> Most Commonly Used:	Morphine (20%)	Oxycodone (25%)	Morphine (23%)	Morphine (18%)	Hydromorphone (11%)
3 <sup>rd</sup> Most Commonly Used:	Fentanyl (20%)	Morphine (23%)	Oxycodone (18%)	Hydromorphone (10%)	Buprenorphine (10%)
4 <sup>th</sup> Most Commonly Used:	Tapentadol (5%)	Tapentadol (5%)	Oxymorphone (11%)	Fentanyl (11%)	Oxycodone (5%)
5 <sup>th</sup> Most Commonly Used:	Buprenorphine (5%)	Buprenorphine (5%)	Hydromorphone (10%)	Buprenorphine (9%)	Oxymorphone (5%)
Source: ATU Wave 3			Don't use this many opioids (4%)	Don't use this many opioids (18%)	Don't use this many opioids (47%)

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## Performance Overview

- TRx and Market Share
- Units by Strength
- DACON
- Pricing
- Line of Therapy

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## Performance Overview Summary



- Since launch, EXALGO® has enjoyed steady growth, spiking recently to an all-time high due to the manufacturing issues facing Opana ER.
- Similarly, the EXALGO® market share achieved an all-time high, exceeding 2%.
- The mix of EXALGO® units and DAICON remained virtually unchanged, seemingly independent of the overall brand growth.
- EXALGO® ranks as the most expensive product among the competitive set, although the co-pay for EXALGO® is relatively comparable to generics.
- While Opana ER is often used as first or second line therapy, EXALGO® is much more often relegated to a later stage; in response, the EXALGO® market share for fourth line therapy is high, even though the volume of fourth line TRx's is low.

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## Performance Overview



- TRx and Market Share
- Units by Strength
- DACON
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- Line of Therapy

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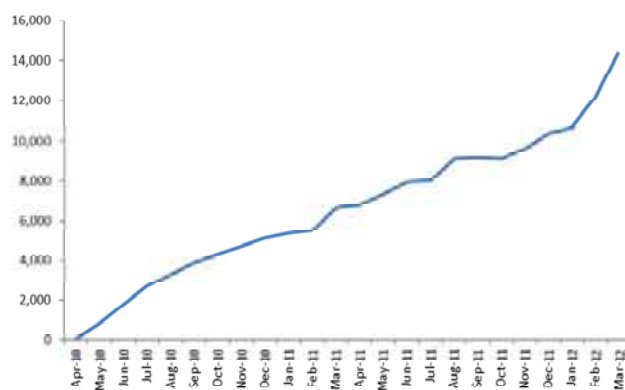
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**In the last 24 months, EXALGO® TRx volume continually increased and picked up pace in the latest three months.**

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### EXALGO® TRx Performance



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2010 through March 2012.

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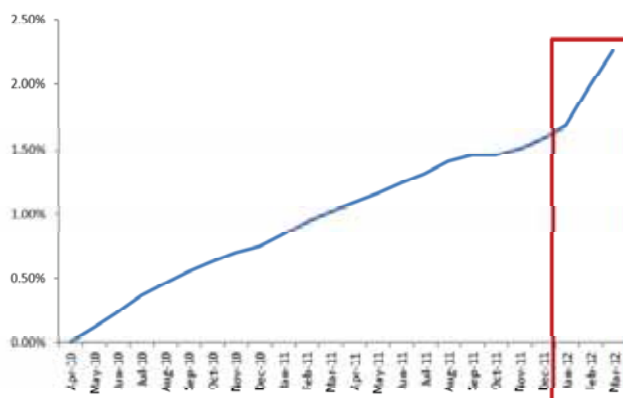
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Likewise, EXALGO® TRx share increased sharply in the last three months, gaining nearly half a share point compared to the prior three months.

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### EXALGO® TRx Market Share Performance



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2010 through March 2012.

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## Performance Overview



- TRx and Market Share
- Units by Strength
- DACON
- Pricing
- Line of Therapy

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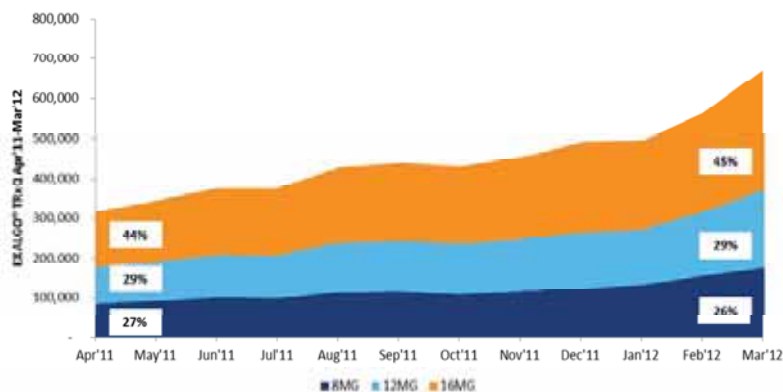
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While EXALGO® TRx has doubled over the past year, the proportion of 16mg to 12mg to 8 mg Units has remained the same.

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### EXALGO® Units by Strength



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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## Performance Overview

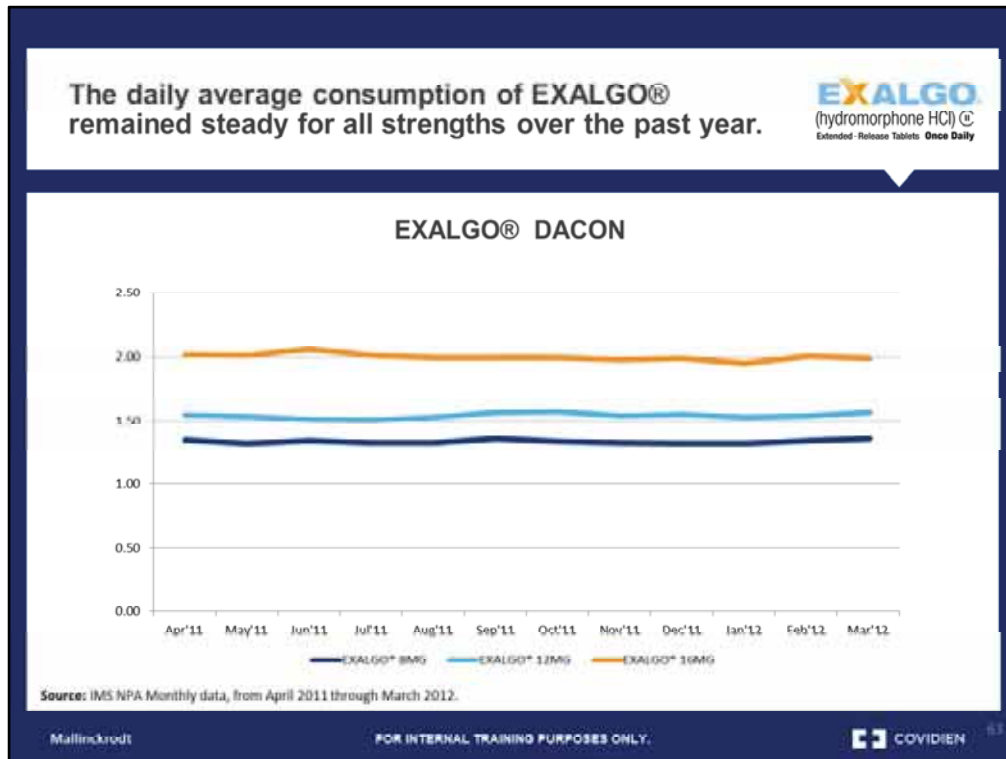
- TRx and Market Share
- Units by Strength
- DACON
- Pricing
- Line of Therapy

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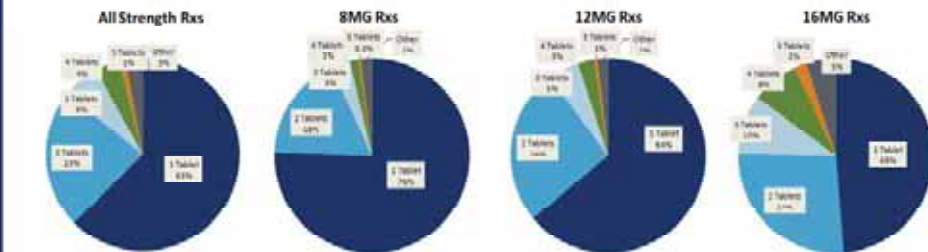
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Almost 2/3 of the EXALGO® TRx's are for one tablet, while just over half of the 16mg TRx's are for more than one tablet.

**EXALGO**  
(hydromorphone HCl) ©  
Extended-Release Tablets **Once Daily**

- 63% of all EXALGO® Rx's are for one tablet per day.
- 23% of all Rx's are for two tablets a day.
- Only 49% of 16 mg Rx's are for one tablet per day.
  - 51% of 16 mg Rx's are for multiple tablets per day.
  - 27% are for 2 tablets per day.
  - 20% of Rx's are for between 3 to 5 tablets per day.



Source: IMS LRx Xponent™

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## Performance Overview

- TRx and Market Share
- Units by Strength
- DACON
- Pricing
- Line of Therapy



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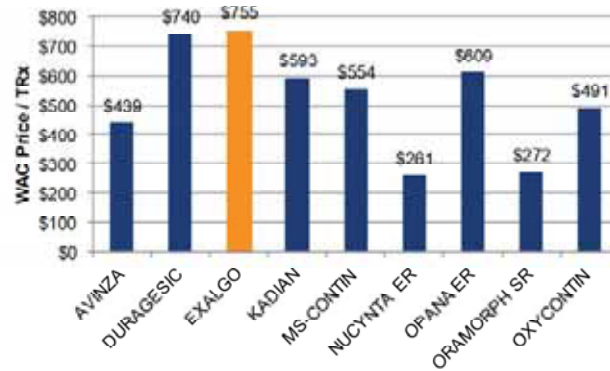
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Considering Average WAC \$/TRx, EXALGO® is the most expensive of the branded pain products.

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### Competitive Price Comparison



Nucynta ER is the least expensive owing to its lower price per tablet and dacon of 2 tablets per day.

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**EXALGO®** offers a competitive co-pay relative to the generic products.

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### Competitive Price Comparison

	Promoted Co-pay	Max. Monthly Value	Expiration
Avinza	N/A	\$30	N/A
Duragesic	N/A	\$50	6/30/2012
<b>EXALGO®</b>	\$15	\$60	12/31/2012
Kadian	N/A	N/A	N/A
M3 Contin	N/A	N/A	N/A
Nucynta ER	\$25	\$100	12 mo.
Opana ER	\$20	\$25	12 prescriptions
Oramorph SR	N/A	N/A	N/A
Oxycontin	N/A	\$70	N/A

Nucynta ER offers the most competitive value proposition relative to the market basket.

Opana ER offers the weakest value proposition on a monthly value basis.

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## Performance Overview

- TRx and Market Share
- Units by Strength
- DACON
- Pricing
- Line of Therapy



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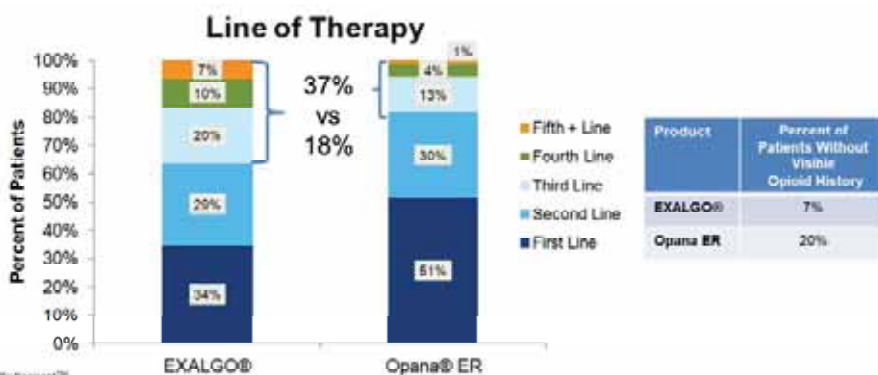
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Opana ER patients are more likely to receive the treatment as their *first line or second line*; more EXALGO® patients receive EXALGO® later.

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#### ER Line of Therapy Comparison for Patients on EXALGO® and Opana ER



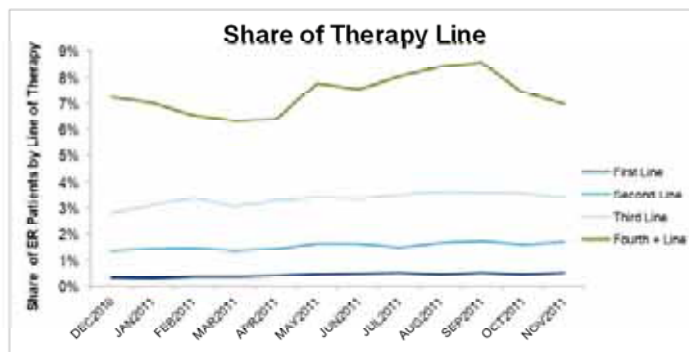
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**EXALGO®** enjoyed the highest LAO market share with 4<sup>th</sup>+ line use; unfortunately, the 4<sup>th</sup>+ volume is relatively small.

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	First Line	Second Line	Third Line	Fourth + Line
ER Market Sample Size	1,178,492	316,492	98,246	38,184
EXALGO® Sample Size	5,168	4,901	3,295	2,661

Source: IMS LRx Xponent™

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(hydromorphone HCl) 

Extended-Release Tablets **Once Daily**

## EXALGO® Profile

- Product Profile
- Positioning and Messaging
- Patient Illustration
- HCP Perceptions
- SWOT

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## EXALGO® Profile Summary



- The EXALGO® product profile fits its use—a potent hydromorphone that reaches peak concentrations slowly, allowing for once a day dosing.
- The EXALGO® Brand Essence focuses on the comfort of both Patients and Physicians, and the positioning is as a once daily, dependable solution for chronic pain, focusing on the clinical attributes of the product.
- The target patients for EXALGO® have previously taken either an oxycodone or a hydrocodone and otherwise largely resemble the target patients of competitors.
- Many physicians respond favorably to the EXALGO® message and positioning, but in general, physicians view the product as similar to other branded Step 3 products except that they perceive the managed care coverage and the available dosing as weaknesses specifically for EXALGO®.
- Indeed, half of physicians cite cost/insurance concerns as the primary reason for not prescribing EXALGO® to more patients with moderate to severe chronic pain.

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**EXALGO**  
(hydromorphone HCl)   
*Extended-Release Tablets* **Once Daily**

## EXALGO® Profile



- Product Profile
- Positioning and Messaging
- Patient Illustration
- HCP Perceptions
- SWOT

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The EXALGO® product profile fits its use—a potent hydromorphone that reaches peak concentrations slowly, allowing for once a day dosing.

**EXALGO**  
(hydromorphone HCl) ©  
Extended-Release Tablets Once Daily

<b>Description</b>	EXALGO® tablets contain hydromorphone hydrochloride, a mu-opioid agonist. Utilizing the OROS® delivery system, EXALGO® gradually and consistently releases hydromorphone for once-daily dosing.
<b>Indication</b>	EXALGO® is an opioid agonist indicated for once daily administration for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time.
<b>Pharmacokinetics</b>	<ul style="list-style-type: none"> <li>Compared to IR hydromorphone, EXALGO® reaches peak concentrations more slowly and has a lower C<sub>max</sub></li> <li>Plasma levels rise for the first 6 to 8 hours after the initial dose</li> <li>EXALGO® reaches steady-state concentrations in 3 to 4 days</li> <li>At steady state, EXALGO® provides a more stable and consistent concentration of hydromorphone than immediate-release hydromorphone</li> <li>Consuming alcohol does not significantly alter the release of EXALGO® into the blood stream. Drug release is also generally unaffected by the presence of food.</li> </ul>
<b>Efficacy</b>	<ul style="list-style-type: none"> <li>EXALGO® reduced mean pain intensity (numerical rating scale) by 50% in successfully converted patients during the conversion/titration phase (6.4 at week 1, 3.2 at week 4)</li> <li>The placebo group had an increase in median pain intensity scores 8x the increase in pain intensity scores found in the EXALGO® group from baseline to week 12 (1.6 vs 0.2, respectively)</li> </ul>
<b>Metabolism</b>	<ul style="list-style-type: none"> <li>Hydromorphone is the active metabolite of hydrocodone</li> <li>EXALGO® (hydromorphone) is not metabolized by CYP450 and has no active metabolites</li> </ul>
<b>Dosing and Administration</b>	<ul style="list-style-type: none"> <li>The tablets are to be administered every 24 hours with or without food</li> <li>EXALGO® is available in 8 mg, 12 mg, 16 mg, and 32 mg dosage strength</li> </ul>
<b>Adverse Events</b>	<ul style="list-style-type: none"> <li>Most common adverse reactions (&gt;10%) are: constipation (31%), nausea (28%), vomiting, somnolence, headache, and dizziness</li> </ul>

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The EXALGO® Brand Essence focuses on the comfort of both Patients and Physicians.

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**EXALGO**

- ✦ Gradual onset of action (6 hours)
- ✦ Keeps blood levels steady
- ✦ Only long-acting (24 hours) form
- ✦ Historically familiar
  - Powerful
  - Safe
- ✦ OROS technology

**Resolute**

**Genuine**

**Inspiring**

**Refined**

- ✦ Makes physicians feel comfortable
  - Its efficacy is proven
  - Its safety is proven
  - 6-hour onset
  - Proven OROS technology
- ✦ Makes patients feel comfortable
  - Less pain
  - Able to sleep through the night
  - Won't wear off for 24 hours
- ✦ I (patients) feel protected and comforted
- ✦ I (physicians) feel confident about my choice

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The EXALGO® Brand Essence leverages the concept of “responsible power,” with *powerful pain relief* delivered in a targeted fashion.

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## EXALGO® Profile



- Product Profile
- Positioning and Messaging
- Patient Illustration
- HCP Perceptions
- SWOT

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EXALGO® is positioned as a once daily, dependable solution for chronic pain, focusing on the clinical attributes of the product.

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(hydromorphone HCl)   
Extended-Release Tablets Once Daily

For HCPs treating patients whose chronic pain control is **inadequate** or **burdensome**, EXALGO® is the dependable solution that can be trusted to provide true 24 hour uninterrupted pain relief with one dose.

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The current core messaging—INSPIRE—supports EXALGO®'s positioning.


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Extended-Release Tablets **Once Daily**

- Your confidence promoting EXALGO® will help convince physicians to move it up in their treatment algorithm
- EXALGO® utilizes an **innovative delivery system to treat** chronic pain
- As a once-daily product, EXALGO® should be a **standard** treatment in your practice for opioid-tolerant patients
- To see the value of EXALGO® in action, let's review a **patient illustration**
- To validate EXALGO® efficacy, you need to obtain **real-life** experience in your practice
- Ensure** proper conversion and titration

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## EXALGO® Profile




- Product Profile
- Positioning and Messaging
- Patient Illustration
- HCP Perceptions
- SWOT

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**Current patient illustrations reflect positioning.**

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**Oxycodone patient**

- Experiencing side effects
- Pain not well controlled
- A different molecule may be a logical next step


**Hydrocodone patient**

- Dosing regimen isn't keeping her pain to be well controlled
- Tolerates hydrocodone well
- EXALGO® may be a logical next step since she has been exposed to hydromorphone as an active metabolite of hydrocodone


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## EXALGO® Profile




- Product Profile
- Positioning and Messaging
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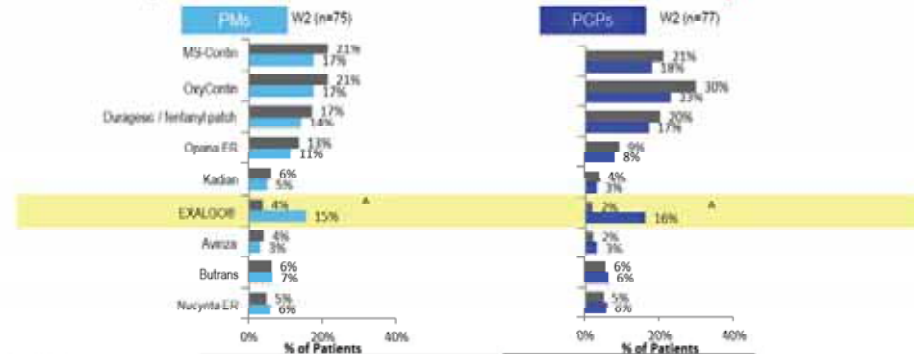
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After reviewing the positioning statements, physicians anticipate 15-16% of patients able to tolerate hydrocodone will receive EXALGO® in the future.

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**Post-Positioning: Prescribing for Last/Next 20 Patients Able to Tolerate Hydrocodone**



Q added W2

Base = Total Physicians (base var)

Q11a Of your last 20 patients able to tolerate hydrocodone whom you switched from an immediate-release agent to an extended-release product, how many did you prescribe each of the following?

Q43 Taking into consideration these two statements about EXALGO® and thinking about your next 20 patients able to tolerate hydrocodone whom you will switch from an immediate-release agent to an extended-release product, what number of these patients would receive each of the following?

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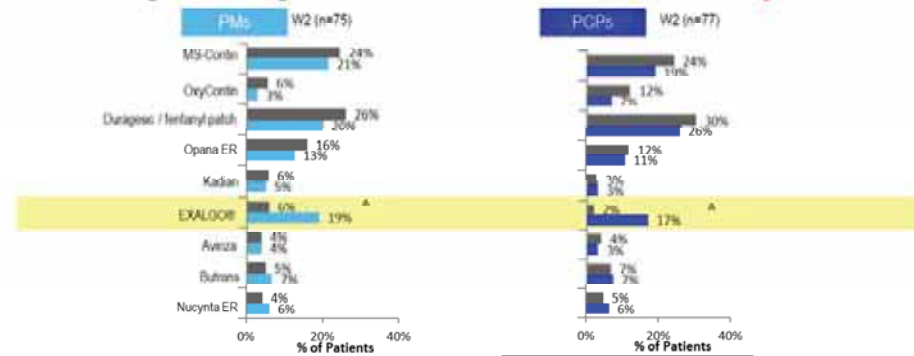
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Post-review of positioning statements, physicians anticipate 17-19% of patients unable to tolerate oxycodone will receive EXALGO® in the future.

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Post-Positioning: Prescribing for Last/Next 20 Patients Unable to Tolerate Oxycodone



Q added W2

Base = Total Physicians (bases vary)

Q11c Of your last 20 patients unable to tolerate oxycodone, how many did you switch to each of the following extended-release agents?

Q44 Taking into consideration these two statements about EXALGO® and thinking about your next 20 patients unable to tolerate oxycodone, what number of these patients would you switch to each of the following?

Note: Legend matches PMPs chart; PCPs chart follows the same pattern

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**A prescribing exercise for hypothetical patient types requiring higher strength doses of ER opioids was conducted (W3ATU).**

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**Patient A: OxyContin**

- Working 48 year old male, 5'10", 207 pounds
- Non-neuropathic chronic low back pain that is moderate to moderately severe in intensity
- Continues to complete physical therapy with little pain relief
- Inadequate pain control after 4 months; increased dose of current medication

**Pain medication progression**

- OxyContin (oxycodone) started on 20 mg BID but needed to be titrated to 60 mg BID over a period of several months.
- Percocet (oxycodone 5 mg/acetaminophen 325 mg) 1 tablet up to 4 times a day for breakthrough pain.
- Titrated to OxyContin 60 mg BID two weeks prior.
- Continues to have inadequate control of pain.

**Other concomitant medications**

- Omeprazole 20 mg/day for acid reflux (2 years)
- Atorvastatin 40 mg/day for hyperlipidemia
- Diltiazem 180 mg/day for hypertension

**Patient B: Hydrocodone**

- 38 year old female, 5'4", 135 pounds
- Nonspecific chronic low back pain of moderate intensity resulting from an injury
- Continues to complete physical therapy with little pain relief

**Pain medication progression**

- Ibuprofen 800 mg TID
  1. GI complications and inadequate pain relief
- Norco (hydrocodone 7.5 mg/acetaminophen 325 mg) PRN for pain
  1. Pain was persistent, so dosing schedule was changed to every 6 hours around the clock
  2. Over the past 6 months, Norco has been increased to 10/325mg every 6 hours around the clock
- Continues to have inadequate control of pain

**Other concomitant medications**

- Citalopram 40 mg/day for depression

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**PMs are more likely than PCPs to select EXALGO® for Patient A (OxyContin); however, Duragesic, MS-Contin and Opana ER were also considered.**

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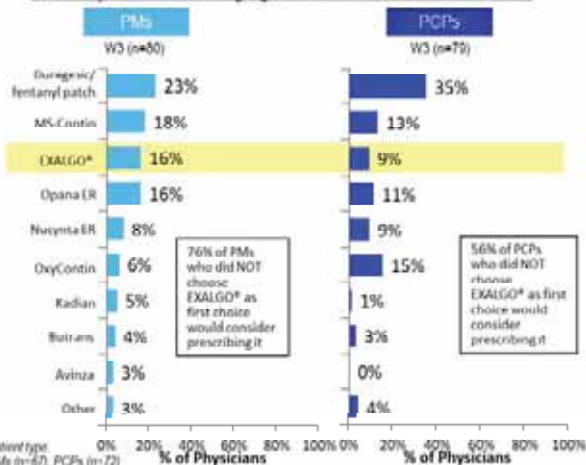
### Patient A

#### Pain medication progression

- OxyContin (oxycodone) started on 20 mg BID but needed to be titrated to 60 mg BID over a period of several months.
- Percocet (oxycodone 5 mg/acetaminophen 325 mg) 1 tablet up to 4 times a day for breakthrough pain.
- Titrated to OxyContin 60 mg BID two weeks prior.
- Continues to have inadequate control of pain.

Patient A is currently taking **120 mg of OxyContin daily**, which is equivalent to **48 mg EXALGO®**

#### % of Physicians Selecting Agent as First Choice for Patient A



O added W3

Base = Total Physicians: PMs (n=80); PCPs (n=79)

Q64 Please choose which agent you would prescribe for each patient type.

Base = Physicians who did not select EXALGO® as first choice: PMs (n=47); PCPs (n=72)

Q64a Would you consider prescribing EXALGO® (hydromorphone HCl extended release tablets) for Patient A?

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PMs were also more likely than PCPs to select EXALGO® for Patient B (Hydrocodone); however, for this patient Butrans and Nucynta ER were considered.

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### Patient B

#### Pain medication progression

- Ibuprofen 800 mg TID
  1. GI complications and inadequate pain relief
- Norco (hydrocodone 7.5 mg/acetaminophen 325 mg) PRN for pain
  1. Pain was persistent, so dosing schedule was changed to every 6 hours around the clock
  2. Over the past 6 months, Norco has been increased to 10/325mg every 6 hours around the clock
- Continues to have inadequate control of pain

↓

Patient B is currently taking 40 mg of hydrocodone daily, which is equivalent to 16 mg EXALGO®

Q added W3

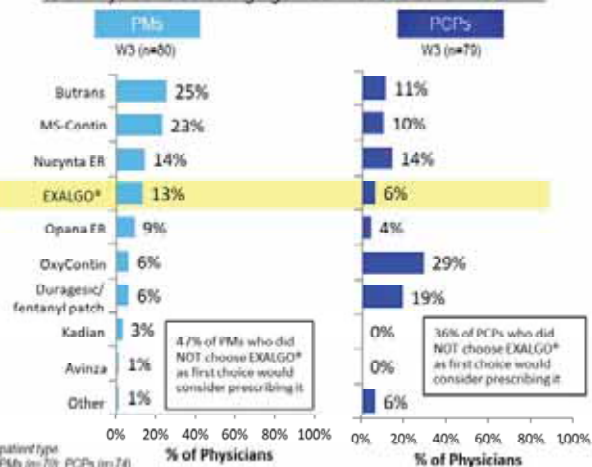
Base = Total Physicians: PMs (n=80); PCPs (n=79)

Q64 Please choose which agent you would prescribe for each patient type.

Base = Physicians who did not select EXALGO® as first choice: PMs (n=70); PCPs (n=74)

Q64b Would you consider prescribing EXALGO® (hydromorphone HCl extended release tablets) for Patient B?

#### % of Physicians Selecting Agent as First Choice for Patient B



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PMs perceive EXALGO® to be superior than OxyContin on many clinical attributes but worse on insurance coverage and available strengths.

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#### EXALGO® Performance vs. Key Competitors among PMs

Attribute-Listed by stated importance	Opana ER	Oxy Contin	Butrans	Nucynta ER
Duration of pain relief				
Insurance coverage				
Difficult to abuse				
Side effect profile				
Efficacy across types of pain				
Efficacy of Molecule				
Maintaining steady state				
Patient is able to tolerate the analgesically active metabolite				
Patient is able to tolerate the parent molecule				
Potential for drug-drug interaction				
Dosing interval				
Number of available dosage strengths				
Time to steady state				
No active metabolites				

EXALGO® performs worse  
At parity  
EXALGO® performs better - Based on statistical significance

(Base = Physicians who are familiar or prescribe agent (bases vary by agent))

Q19: Please rate each of the following brands on the attributes listed below using a scale from 1 to 7, where a "1" means "Does not describe at all" and a "7" means "Describes very well".

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PCPs were more likely to view EXALGO® as equivalent to OxyContin on most features, also giving the agent lower ratings on insurance coverage.

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#### EXALGO® Performance vs. Key Competitors among PCPs

Attribute-Listed by stated importance	Opana ER	OxyContin	Butrans	Nucynta ER
Duration of pain relief				
Insurance coverage				
Difficult to abuse				
Side effect profile				
Efficacy across types of pain				
Efficacy of Molecule				
Maintaining steady state				
Patient is able to tolerate the analgesically active metabolite				
Patient is able to tolerate the parent molecule				
Potential for drug-drug interaction				
Dosing interval				
Number of available dosage strengths				
Time to steady state				
No active metabolites				

EXALGO® performs worse  
At parity  
EXALGO® performs better - Based on statistical significance

(Base = Physicians who are familiar or prescribe agent (bases vary by agent))

Q19 Please rate each of the following brands on the attributes listed below using a scale from 1 to 7, where a "1" means "Does not describe at all" and a "7" means "Describes very well".

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Half of physicians cite cost/insurance concerns as the primary reason for not prescribing EXALGO® to more patients with moderate to severe chronic pain.

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Top Reasons for Not Prescribing EXALGO® to More Patients with Moderate to Severe Chronic Pain

	PMs		PCPs	
	W2 (n=75)	W3 (n=80)	W2 (n=77)	W3 (n=79)
▪ <b>Cost/Insurance/Formulary concerns (Net)</b>	<b>50%</b>	<b>56%</b>	<b>69%</b>	<b>52%</b>
➤ Insurance coverage concerns	32%	41%	38%	28%
➤ Cost/not cost-effective/high co-pay	9%	33%	23%	29%
➤ Formulary status concerns	9%	3%	8%	4%
▪ <b>Too new/more familiar with other medications</b>	<b>38%</b>	<b>11%</b>	<b>15%</b>	<b>44%</b>

Q added W1

Base = Total Physicians (bases vary)


Q34c: What are the primary reasons you are not prescribing EXALGO® to more of your patients with moderate to severe chronic pain? (OPEN END)


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## EXALGO® Profile

- Product Profile
- Positioning and Messaging
- Patient Illustration
- HCP Perceptions
- SWOT




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## EXALGO® SWOT Analysis



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Strengths	Weaknesses
<ul style="list-style-type: none"> <li>✖ Once daily dosing</li> <li>✖ Delivery system yields steady and consistent PK profile</li> <li>✖ Hydromorphone efficacy</li> <li>✖ Demonstrated safety record and commitment</li> <li>✖ No CYP450</li> </ul>	<ul style="list-style-type: none"> <li>✖ Perceived as Dilaudid</li> <li>✖ Poor patient persistence</li> <li>✖ Limited strength options</li> <li>✖ Limited resources (Sales force, MSLs, National Accounts &amp; A&amp;P spend)</li> <li>✖ Lifecycle timeline</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>✖ Develop and strongly position EXALGO® in the treatment algorithm</li> <li>✖ Commercial Managed Care coverage pull through</li> <li>✖ 32mg launch</li> <li>✖ Decline in competitor promotional focus</li> <li>✖ Hospital use of IR hydromorphone</li> <li>✖ Teaching proper conversion and titration</li> <li>✖ Enhanced KOL relationships</li> </ul>	<ul style="list-style-type: none"> <li>✖ Physician and patient discontinuation</li> <li>✖ New brand and generic entrants (i.e., Remoxy, Opana TR)</li> <li>✖ EXALGO®generics</li> <li>✖ Increased government influence</li> <li>✖ New class wide REMS</li> <li>✖ MHC pricing reaction</li> </ul>

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## Managed Care Analysis

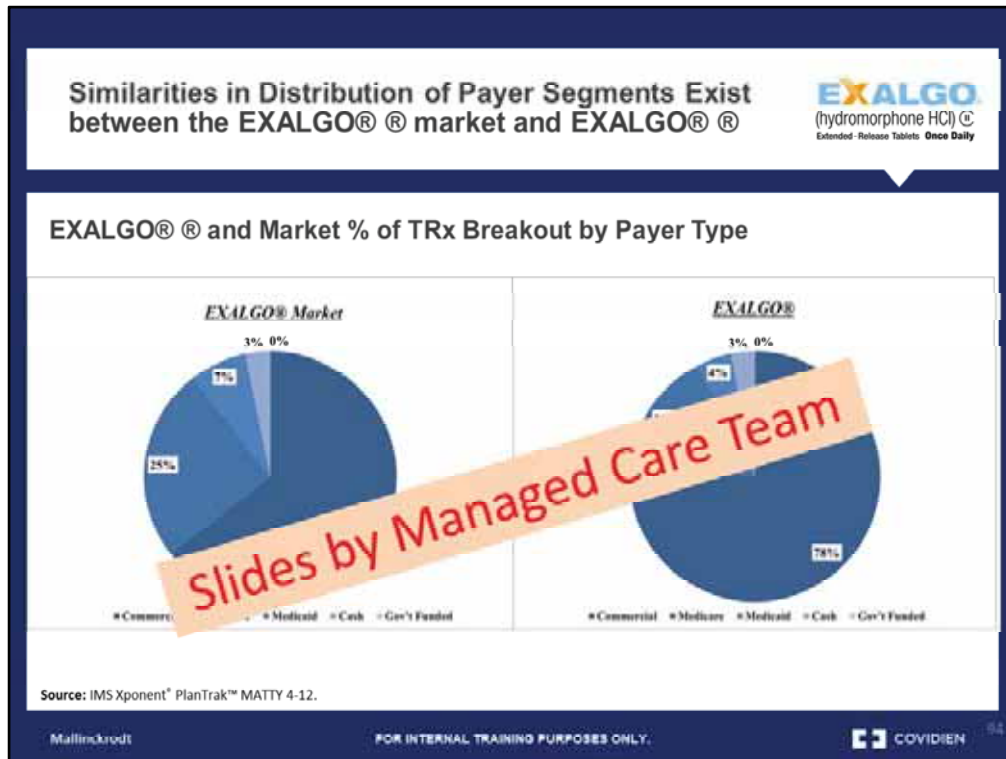
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## Top Commercial Payers



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<i>Payer</i>	<i>% of Market</i>	<i>% of EXALGO®</i>	<i>EXALGO® Mkt Share</i>	<i>EXALGO® Coverage</i>


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## Top Medicare Part-D Payers




Payer	% of Market	% of EXALGO®	EXALGO® Mkt Share	EXALGO® Coverage

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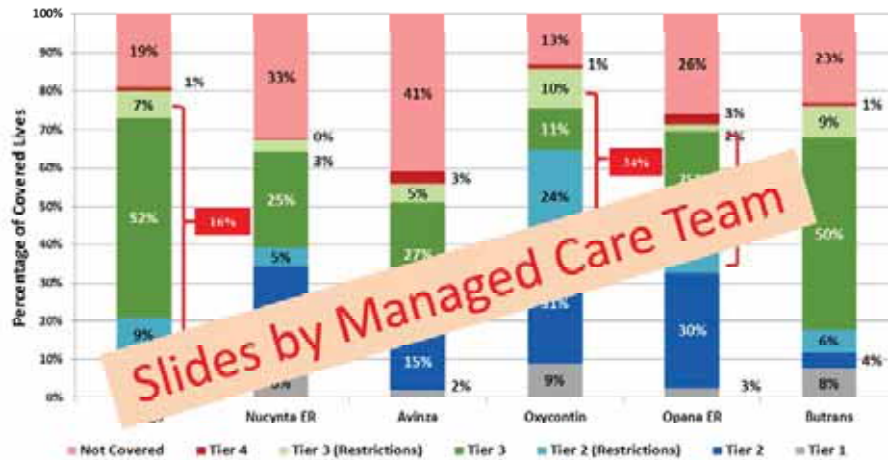
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## EXALGO® Market Coverage Overview

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## Placeholder



- EX vs Opana ER and OxyContin
  - Covered with no restriction
  - Covered with restrictions
  - Not covered
- Bar chart

**Slides by Managed Care Team**

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## Commercial Contract Performance

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## Regional/District Performance




(hydromorphone HCl) ©  
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<i>Region/District</i>	<i>Market TRxs</i>	<i>EXALGO® TRxs</i>	<i>EXALGO® Mkt Share</i>	<i>EXALGO® TRx Growth</i>

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## Part-D Contract Performance

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## Regional/District Performance




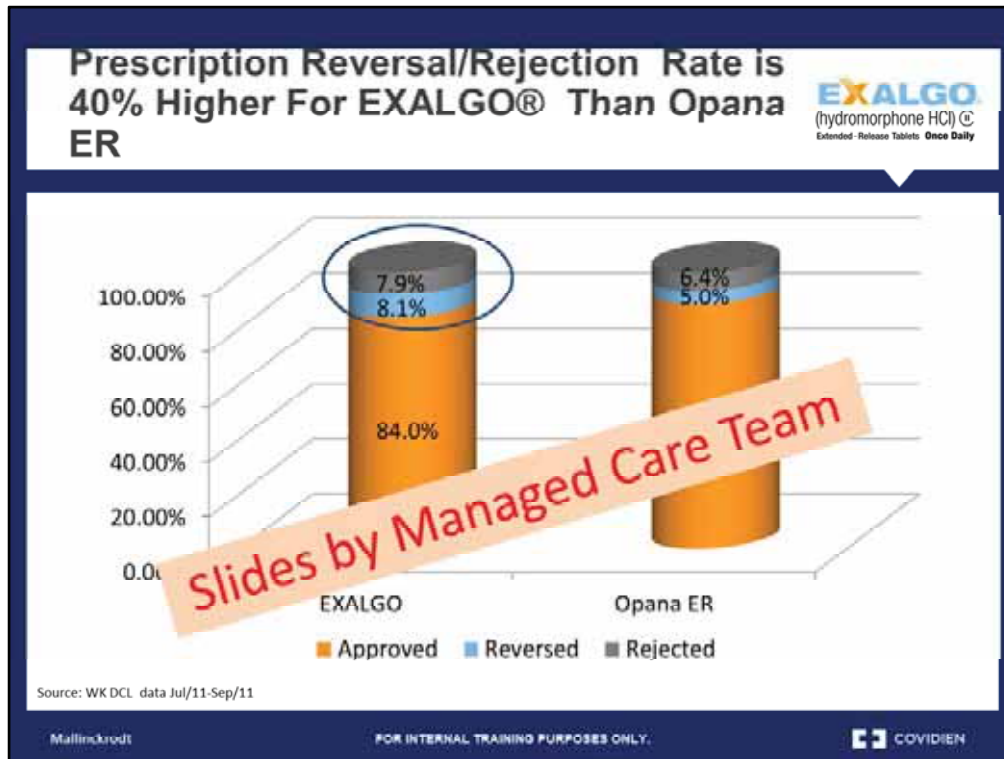
(hydromorphone HCl) ©  
Extended-Release Tablets **Once Daily**

<i>Region/District</i>	<i>Market TRxs</i>	<i>EXALGO® TRxs</i>	<i>EXALGO® Mkt Share</i>	<i>EXALGO® TRx Growth</i>

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## HCP Prescribing Behavior



- Overview
- Decile Analysis
- Discontinuance
- Adoption Dynamics

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## Overview Summary



- Launch to date, 8,259 prescribers have written EXALGO® at least once.
- The number of monthly EXALGO® writers continues to increase over time and reached an all time high in the latest data month.
- Similarly, EXALGO® average productivity has increased over time, surpassing four TRx per prescriber in the most recent data period.
- EXALGO® prescribers who started writing prior to April 2011 (the first year after the launch) contribute the majority of EXALGO® TRx volume.
- In fact, the early adopter cohorts from May, June and July 2010 contribute more than 30% of the most recent three month EXALGO® TRx volume.
- Specialty dynamics for EXALGO® differ from that of the competitive products; for other brands, PCPs contribute a greater percentage of TRx volume than for EXALGO®.

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The total number of monthly prescribers continues to increase over time.

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**EXALGO® TRx Monthly Number of Prescribers**



8,259 prescribers have written at least one EXALGO® TRx LTD

Source: IMS Xponent® PlanTrak™ Monthly data, from April 2010 through March 2012.

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**EXALGO® average productivity has increased over time, surpassing 4 TRx per prescriber in the most recent data month.**

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**EXALGO® TRx Average Productivity per Prescriber**



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2010 through March 2012.

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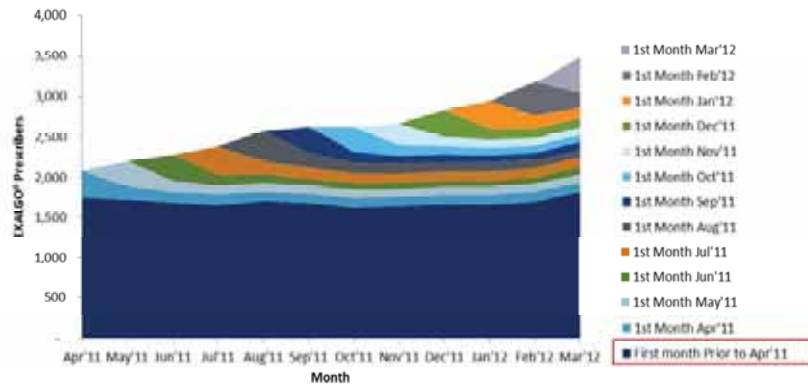
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**COVIDIEN** 108

Each month, a new cohort of writers joins the existing group; the cohort from the first year of launch continues to account for the most writers.



### EXALGO® Prescribers by Writer Cohort



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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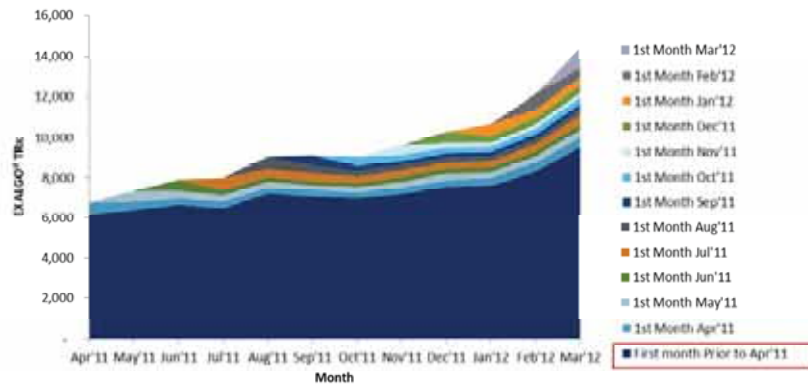
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109

These prescribers, who first wrote prior to April '11, continue to add the most TRx volume growth.

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EXALGO® TRx by Writer Cohort



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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In fact, one third of EXALGO® current three month volume is driven by the earliest adopters from May, June, and July 2010.



**Source:** IMS Xponent® PlanTrak™ Monthly data, from April 2010 through March 2012.

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Anesthesiologists are the largest prescribing specialty for EXALGO® and represent a large percentage relative to the other brands.

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Top Specialties by Brand TRx



NP/PAs represent the fastest growing specialty for EXALGO®.

Source: NPA

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## HCP Prescribing Behavior



- Overview
- Decile Analysis
- Discontinuance
- Adoption Dynamics


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## Decile Analysis Summary



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Physicians in Market Deciles 10 to 8 have the highest PDE/physician ratio.

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Market: EXALGO® •, Oxycontin, Opana ER, Avinaa, Nucynta ER, Butrans  
Mar'12

\*Compound Annual Growth Apr'11-Mar'12

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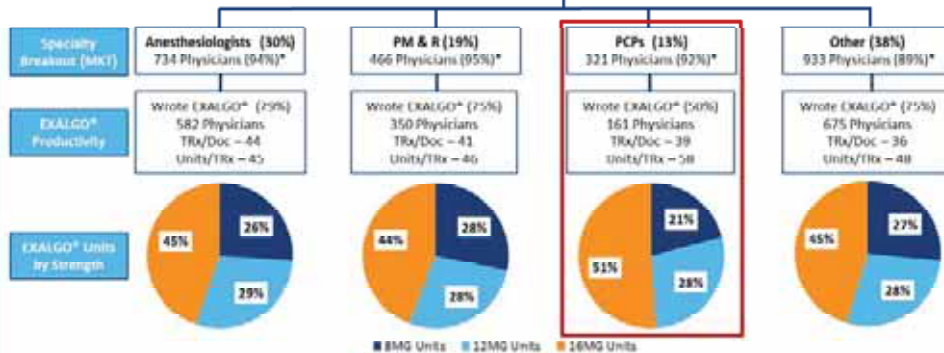
Among the upper EXALGO® Market Decile writers, PCPs write the most units per TRx and are more likely to write the 16mg than the other specialties.

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### EXALGO® Productivity

#### Market Decile 10-8

2,454 Physicians  
(92%)\*



Market: EXALGO® \*, Oxycontin, Opana ER, Avina, Nucynta ER, Butrans

Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012

\*% of Targets

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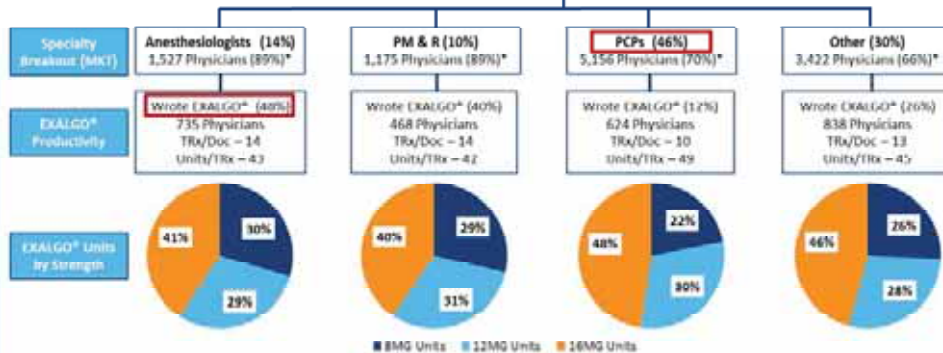
PCPs make up nearly half of Market Deciles 7 to 5,  
but Anesthesiologists make up the majority of the  
EXALGO® Writers.

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### EXALGO® Productivity

#### Market Decile 7-5

11,280 Prescribers  
(79%)\*



Market: EXALGO® \*, Oxycontin, Opana ER, Avinza, Nucynta ER, Bupren.

Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012

\*% of Targets

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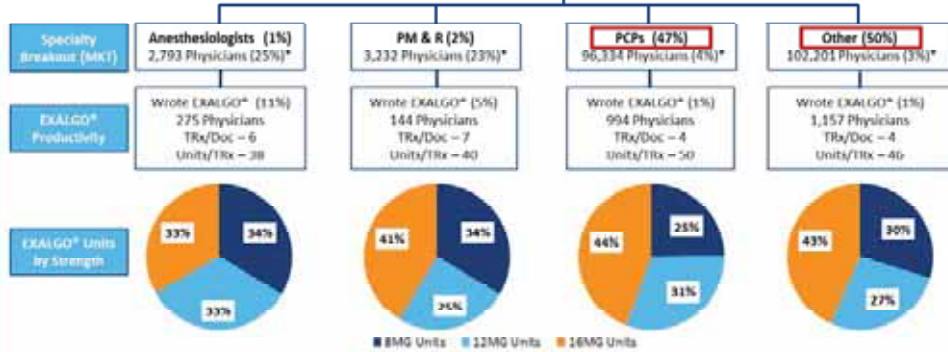
PCPs and other specialties account for nearly all of market deciles 4 to 1; these specialties are also more difficult to convert.

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### EXALGO® Productivity

#### Market Decile 4-1

204,560 Physicians  
(4%)



Market: EXALGO® \*, Oxycontin, Opana ER, Avinza, Nucynta ER, Butrans.

Source: IMS Xponent® PlanTrak® Monthly data, from April 2011 through March 2012.

\*% of Targets

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**For Decile 10 – 8 targets, 75% have prescribed EXALGO® at least once.**

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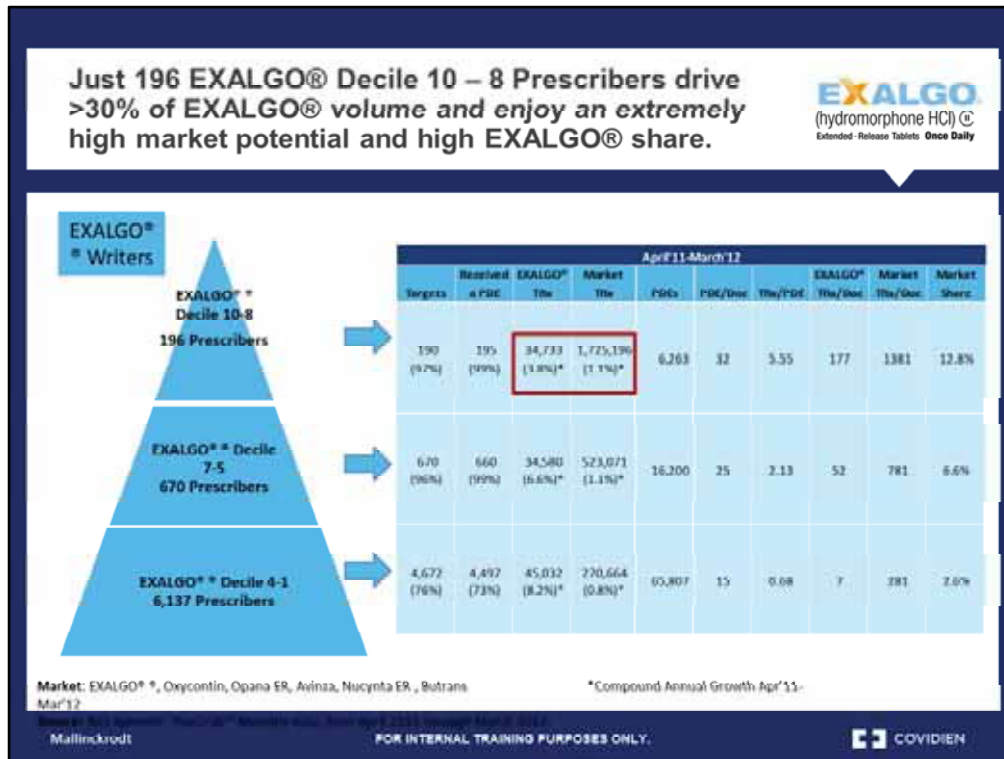
**Market:** EXALGO®\*, Oxycontin, Opana ER, Avinza, Nucynta ER, Butrans  
Mar'12

\*Compound Annual Growth Apr'11-

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40% of EXALGO® prescriptions are coming from EXALGO® Decile 4-1 prescribers, however, these HCPs required 3x the effort (PDEs) to generate these Rx's.

About 88% of EXALGO® prescriptions are driven by the top 2,276 targeted HCPs.



### EXALGO® Prescription Behavior by Targets

EXALGO® TRx Prescription Behavior	# of Targeted HCPs	% of Calls	Total EXALGO® Prescriptions
0	12,954	43%	0
1	1,021	6%	
2	531	4%	
3 to 5	892		
6 to 10	892		6,243
11 to 20		41%	13,997
More than 20		22%	80,471

Updates in Progress

65% of calls have  
12,954  
who have  
not prescribed  
EXALGO®

Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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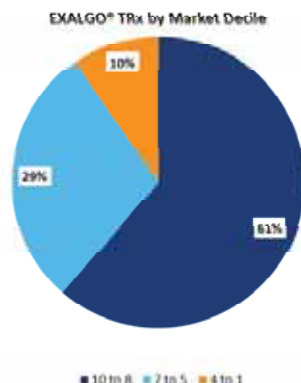
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**EXALGO® prescriptions are driven by high market decile prescribers.**

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### EXALGO® TRx by Market Decile



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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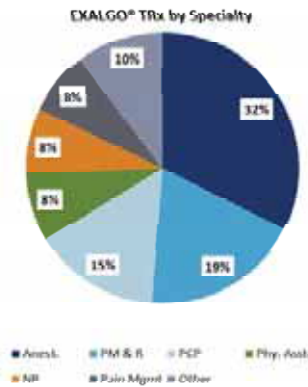
**COVIDIEN** 122



**Anesthesiologists and PM&R Specialists  
disproportionately write EXALGO® Prescriptions.**

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**EXALGO® TRx by Specialty**



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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**COVIDIEN** 178



## HCP Prescribing Behavior

- Overview
- Decile Analysis
- Discontinuance
- Adoption Dynamics



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## Discontinuance Summary

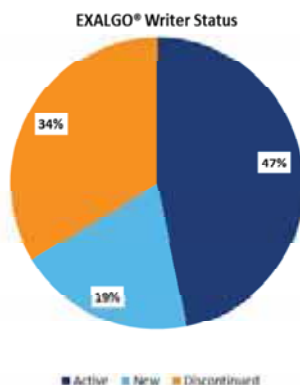


- One third of EXALGO® writers in the last year have discontinued.
- Over half of these Discontinuers were "one and done" prescribers, only trying EXALGO® for one month.
- Opana ER and OxyContin retain more than 85% of the top decile writers (Deciles 5-10) while EXALGO® retains just over 60%.
- Nearly 70% of EXALGO® volume comes from physicians who write all EXALGO® strengths, yet only 25% of writers use all strengths.
- Discontinuers tend to only write one strength.

One-third of the physicians who wrote Exalgo® in the past year have discontinued in the last 3 months.

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### EXALGO® Writer Status In Latest 3 Months



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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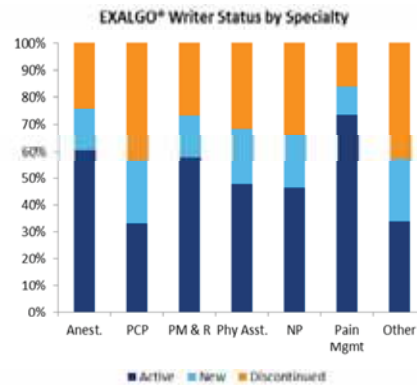
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**COVIDIEN** 178

**PCPs discontinue at a higher rate among the specialties.**

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### EXALGO® Writer Status In Latest 3 Months



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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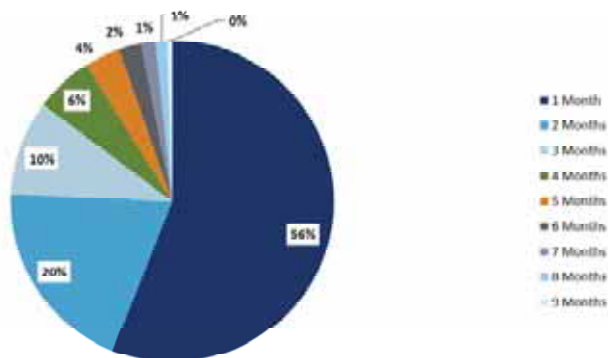
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**COVIDIEN** 177

Over half of the Discontinuers wrote EXALGO® for just one month.

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Months of Writing EXALGO® - Discontinuers



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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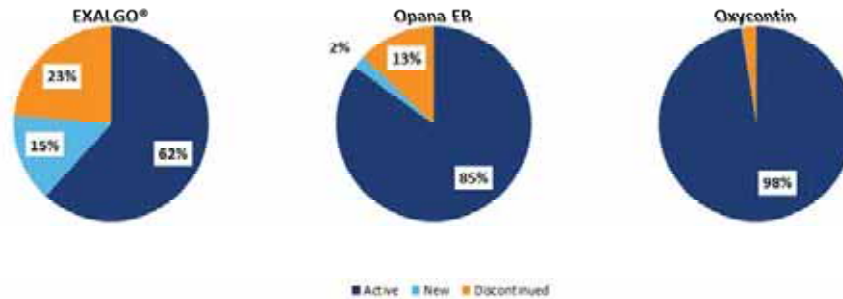
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**COVIDIEN** 128

**EXALGO® has not been able to retain the upper decile writers at the same rate as some of the competition.**

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**EXALGO® Market Writer Status – Market Deciles 10 to 5**



\*Nucynta ER data ranges from 9/11-3/12  
Sources: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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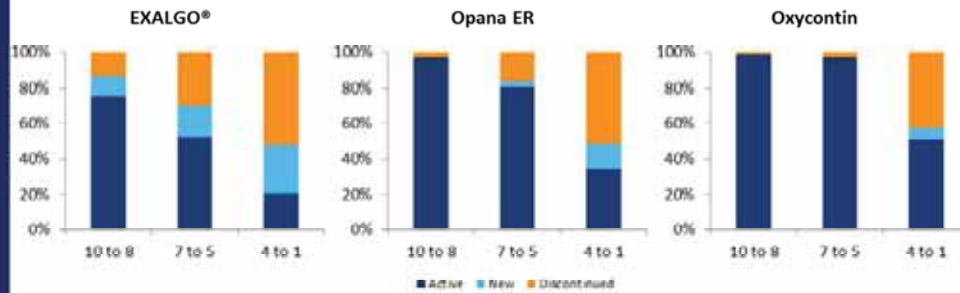
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**COVIDIEN** 129

Opana ER and Oxycontin retained nearly all of the upper decile writers.

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### EXALGO® Market Writer Status by Decile



\*Nucynta ER data ranges from 9/11-3/12

Sources: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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**COVIDIEN** 130

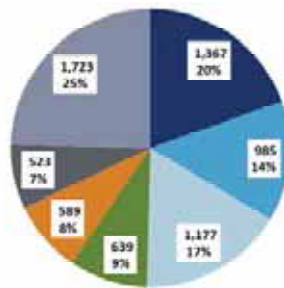


While only 25% of EXALGO® prescribers wrote all strengths, this cohort contributed nearly 70% of EXALGO® TRx volume.

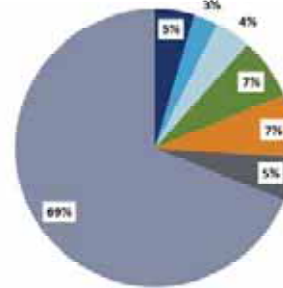


### EXALGO® Prescribers and TRx by Strength

EXALGO® Prescriber Breakout by Prescriber Strength Preference



EXALGO® TRx Breakout by Prescriber Strength Preference



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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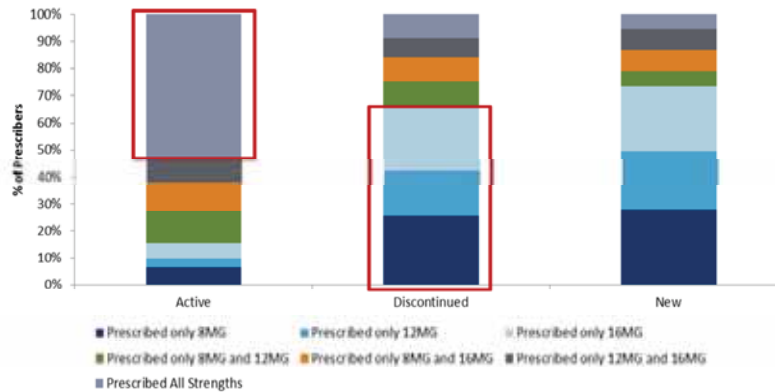
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Over half of the Active prescribers wrote all EXALGO® strengths while two-thirds of Discontinuers only wrote only one strength.

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### EXALGO® Writer Status by Strength Preference – Market Decile 10 to 5



Source: IMS Xponent® PlanTrak™ Monthly data, from April 2011 through March 2012.

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## HCP Prescribing Behavior

- Overview
- Decile Analysis
- Discontinuance
- Adoption Dynamics



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## Successful Adopter Analysis Summary



- “Successful adopters” include EXALGO® targets that have written at least 20 projected Rxs since launch.
- The majority of patients come from successful adopters who demonstrate superior ability to effectively prescribe EXALGO®.
- These physicians are more likely to start patients at better doses, refill/titrate patients, and use breakthrough meds.
- Successful adopters are slightly less likely to start patients on a dose of EXALGO® that is lower than a patient's previous therapy.
- Dabbling physicians have trouble prescribing EXALGO® and are the most likely to lose touch with their patients

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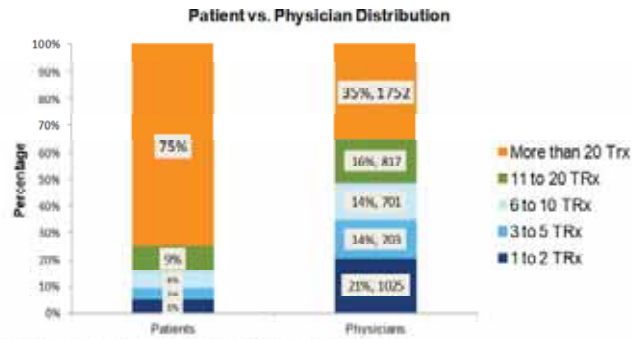
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The dabblers who tried EXALGO® just once or twice represent a large number of physicians (21%) yet a small number of patients (5%).

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### Patient Initiations by Physician Group



\*Counts include only physicians covered in LfA Xponent sample data, which included EXALGO transactions for 77% of prescribers since launch.

Source: IMS Xponent Plantrak™, IMS LfA Xponent™

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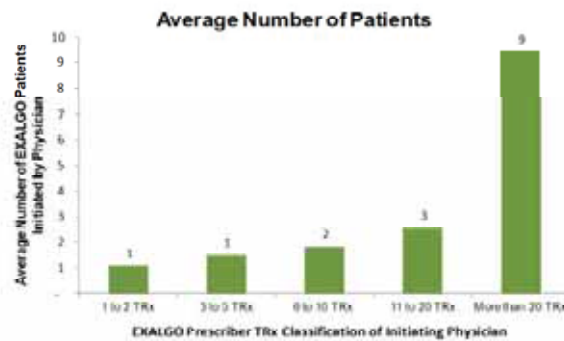
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Maximizing any untapped potential of this group might considerably increase EXALGO® patient counts.

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### Patient Initiations by Physician Group



Source: IMS Xponent Plantrak™, IMS LRx Xponent™

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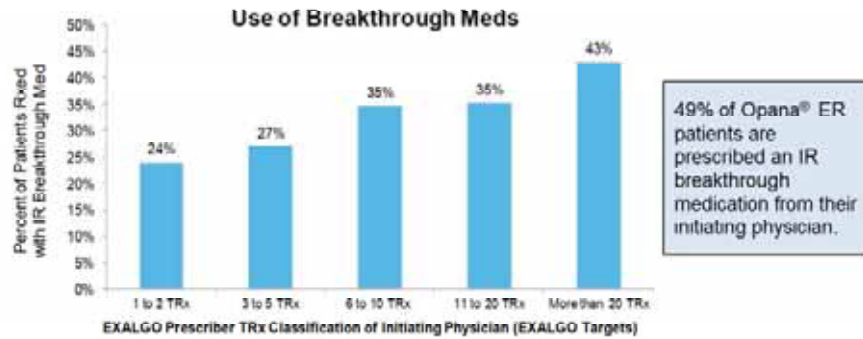
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Physicians who have been more successful with EXALGO® are much more likely to prescribe EXALGO® with a breakthrough IR Medication.

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Use of Breakthrough Medication (Patients could have IR supply on hand already)



Source: IMS Xponent Plantrak™, IMS LfX Xponent™

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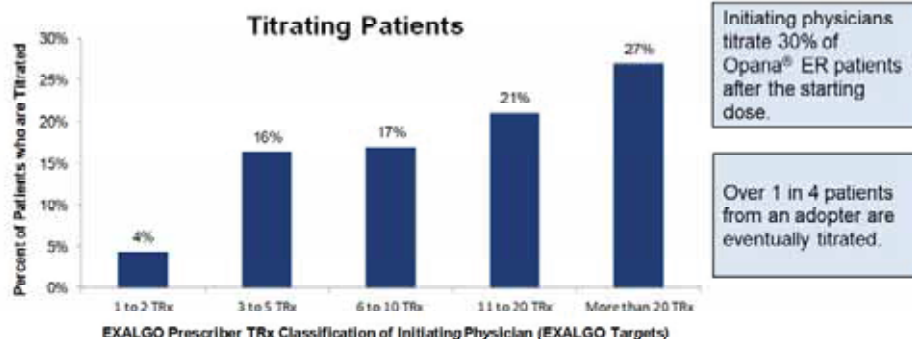
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**Successful EXALGO® Adopters are more likely to titrate patients.**

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### Titration Patterns



Source: IMS Xponent Plantrak™, IMS Lix Xponent™

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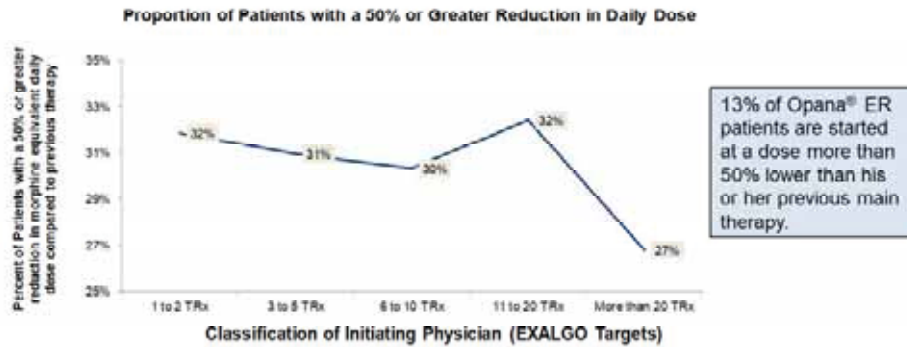
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Successful adopters are somewhat less likely to start a patient on an EXALGO® dose that is more than 50% lower than the patient's previous main therapy dose.

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### Prior Therapy vs. EXALGO® Starting Dose



Source: IMS Xponent Plantrak™, IMS Lix Xponent™

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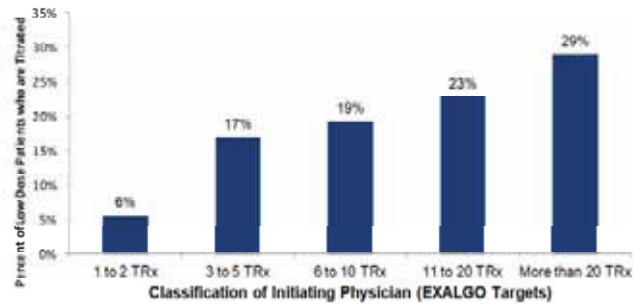
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Physicians with more experience writing EXALGO®  
are the most likely to titrate patients who started at a  
much lower dose than his or her previous therapy.



### Follow Up Treatment for Patients Starting at a Low Dose

#### Titration for Patients who Started at a Dose at least 50% lower than Previous Therapy



Source: IMS Xponent Plantrak™, IMS Lix Xponent™

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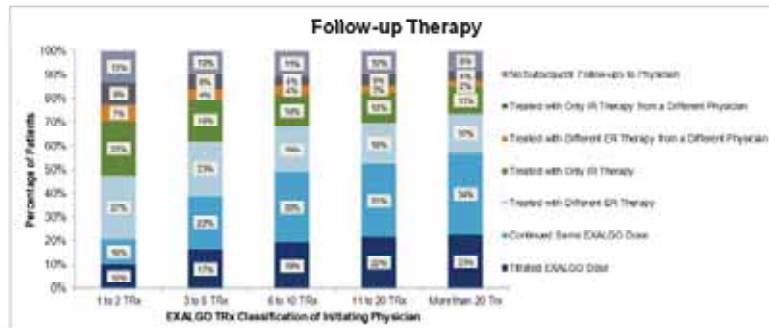
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**Successful adopters are the most likely to titrate the patient as well as prescribe an EXALGO® refill.**

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#### Follow Up Therapy after EXALGO® Initiation

- Dabblers patients are the most likely to switch the patient to a different ER or IR therapy. They are also more likely to have patients who visit a different physician who did not continue EXALGO® therapy.
- Physicians in the 1 to 2 TRx group do not appear to receive feedback from 30% of patients.




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## Patient Behavior




- Overview
- Persistency
- Dosing
- Titration
- Breakthrough Medication Use

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## Patient Behavior Summary



- Patients taking Step 3 prescriptions have on average suffered from chronic pain for more than 10 years, are truly limited by their pain, are more likely female, more often live in the suburbs, and on average are in their mid-40's.
- Overall, EXALGO® patients are less persistent than Opana ER patients.
- Persistency improves for EXALGO® and Opana ER when not used as a first line therapy.
- Patient persistence is correlated to use of breakthrough medication and prior therapy.
- EXALGO® and Opana ER titration behavior is similar with only 30 – 35% of patients titrating their dose; however, the starting dose of Opana ER is much higher than EXALGO®
  - EXALGO® mean daily doses are 78% lower than Opana ER
  - Opana ER median starting dose is 50% higher than EXALGO® median starting dose (90 mg vs 60 mg)
  - Opana ER median final dose after titration is 2.25x the EXALGO® median final dose (180 mg vs 80 mg)

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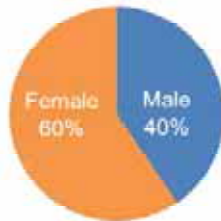
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**Patients tend to be middle aged, suburban, suffering from chronic pain for years, and unemployed.**

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- Average age = 46
- 25% employed full time
- More likely suburban
- On average, suffered from chronic pain for almost ten years

#### Chronic Pain Characteristics

- Pain is linked to many causes, with injury (27%) and arthritis (20%) being the most common
- Patients have chronic pain in multiple locations
  - The vast majority (78%) cite chronic back/spine pain
  - More than half (53%) indicate lower body pain
- Chronic pain “completely interferes” with work and exercise in almost half of patients (48%)
- Patients perceive significant improvements after taking their medication, but pain is not completely suppressed (pain levels go from 9 out of 10, to 4 out of 10)

Source: Patient Segmentation Research, IMA, Fielded May 31<sup>st</sup> and June 13<sup>th</sup>, 2011, n=215

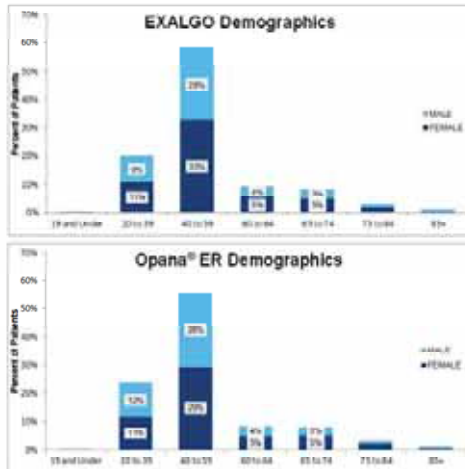
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**EXALGO® and Opana® ER patients tend to be between the age of 40-59.**

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There are more female EXALGO® patients than male patients (57% vs 43%)

Source: IMS Market Dynamics, MAT March 2012

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## Patient Behavior



- Overview
- Persistency
- Dosing
- Titration
- Breakthrough Medication Use

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**Many factors can influence patient persistence, including prior therapy, dosing, titration, and breakthrough medication use.**

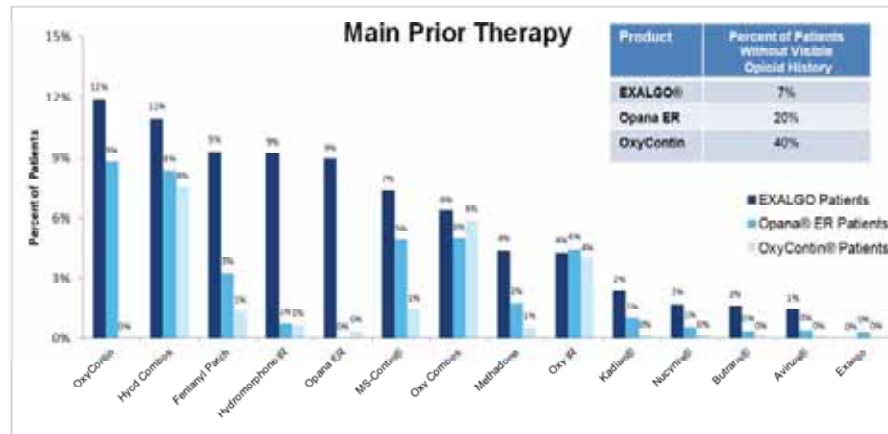
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#### **Key Patient Metrics Reflecting or Influencing Persistence**

- Prior therapy
- Length of therapy
  - At different time points (ex. 30 days or less, greater than 180 days)
  - Means days of therapy
- Average dose
- Titration behavior
- Rescue medication use

**93% of EXALGO® Patients have a visible Opioid History.**

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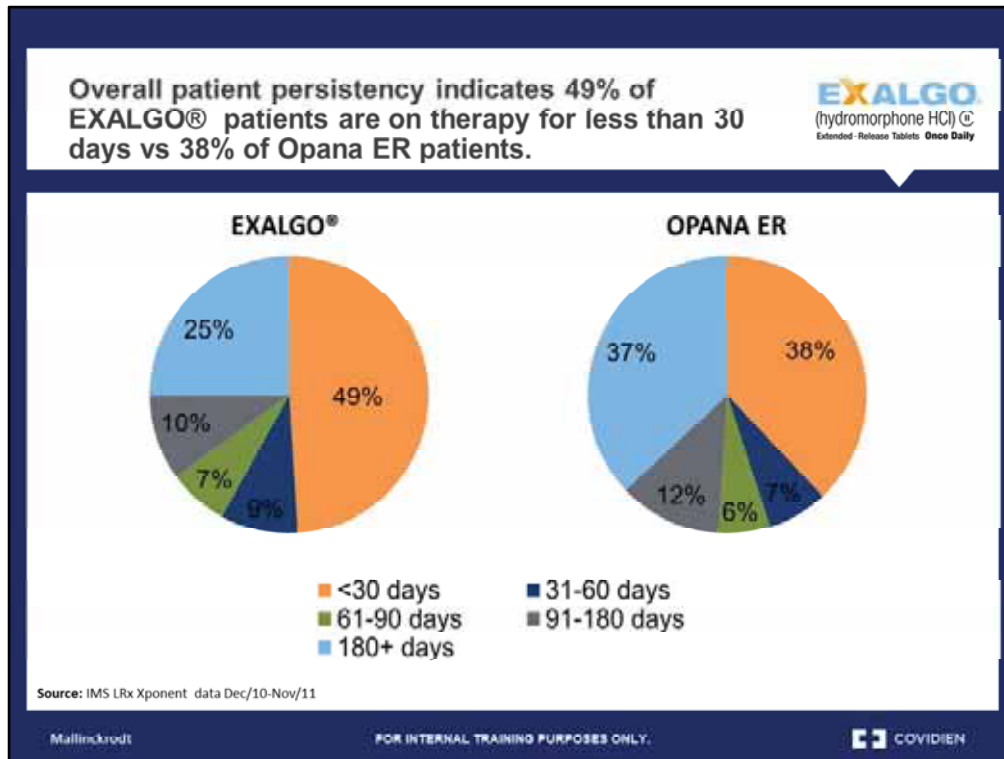
Source: IMS LRx Xponent™

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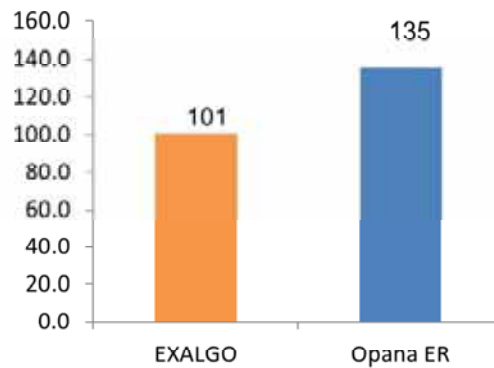




The EXALGO® mean days of therapy are 30% less than Opana ER.

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### Mean Days of Therapy



Product	Median Therapy Days	Mean Therapy Days
EXALGO	37	101
Opana ER	87	135

Source: IMS LRx Xponent, data Dec/10-Nov/11 – calculated using patients starting Dec/10-May/11

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**Persistency varies based on Main Prior Therapy.**

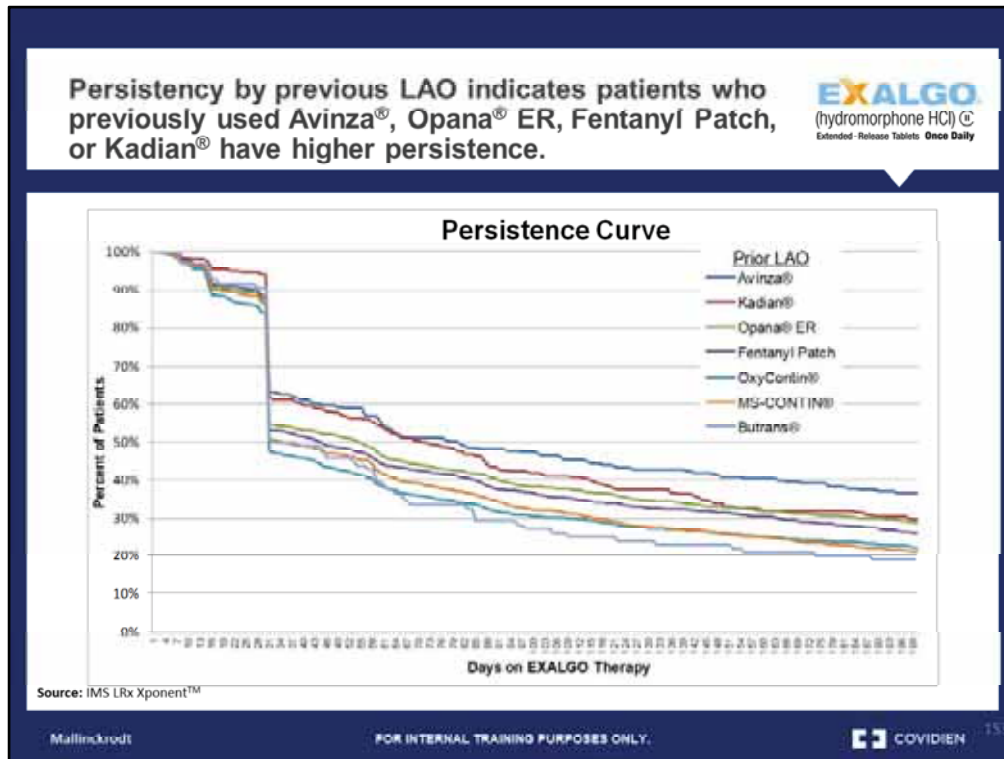
Main Prior Therapy	EXALGO® Median Days of Therapy	Opana® ER Median Days of Therapy	OxyContin® Median Days of Therapy
OxyContin	30	58	N/A
Hyd Combos	30	58	30
Fentanyl Patch	34	59	47
Hydromorphone IR	49	53	30
Opana ER	37	N/A	77
MS-Contin®	30	60	58
Oxy Combos	30	59	30
Methadone	30	57	49
Oxy IR	30	58	30
Kadian®	58	83	87
Nucynta®	30	59	30
Butrans®	30	52	39.5
Avineer®	59	90	90
EXALGO®	N/A	65.5	73

Source: IMS LRx Xponent™

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This chart categorizes EXALGO patients by the previous main therapy. If the main therapy was a LAO, then the patient was included in the persistence curve. The percentage point at each mark on the x axis represents the proportion of patient still on therapy at that point. For instance, at day 60 about 57% of EXALGO patients who previously used Avinza were still on EXALGO therapy.



## Patient Behavior

- Overview
- Persistency
- Dosing
- Titration
- Breakthrough Medication Use

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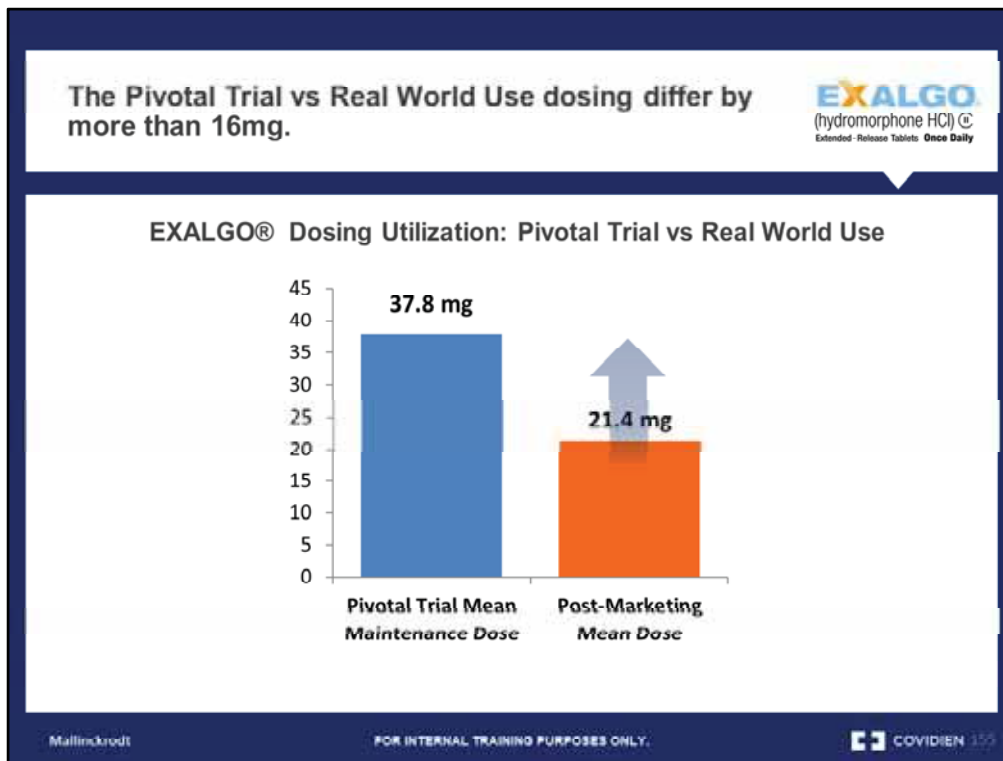
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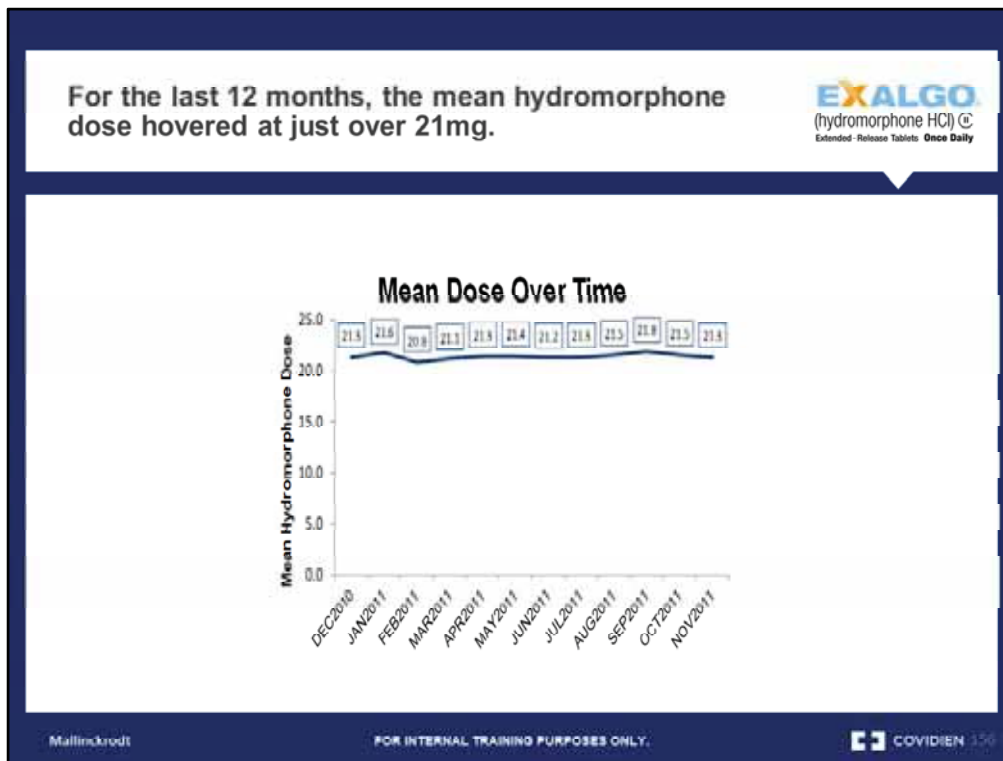
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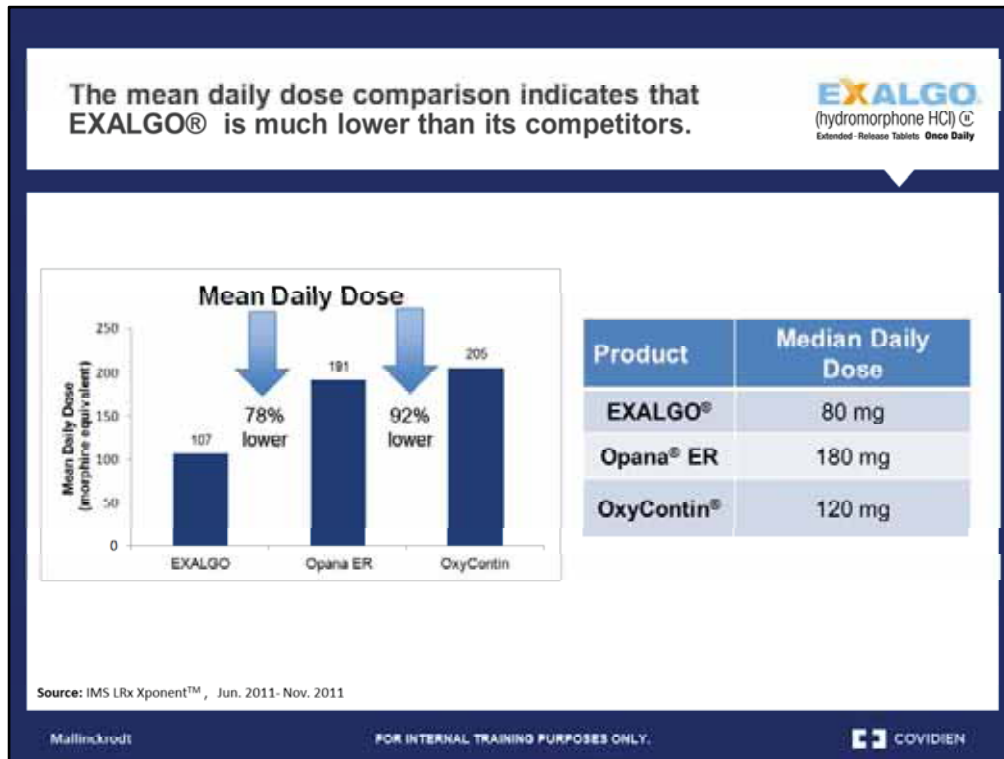
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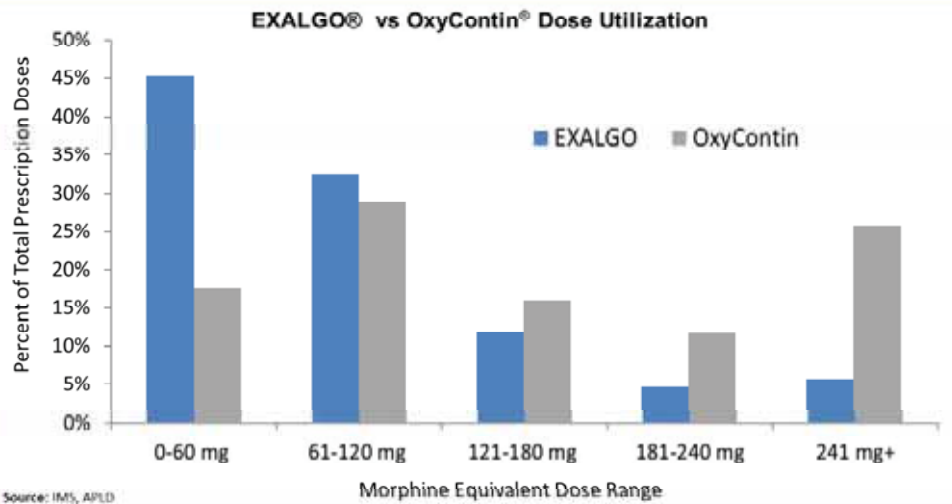




21.4 is mean dose of EXALGO; Opana ER = 63 mg;

Dose utilization data suggests that HCPs treat EXALGO® differently than OxyContin®, writing nearly 45% of TRx for the lowest morphine equivalent dose.

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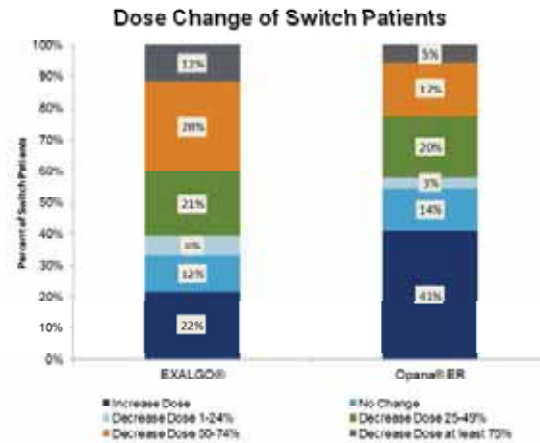
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About 67% of EXALGO® switch patients decreased the equianalgesic dosage, while only 45% of Opana ER switch patients decreased dosage.

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### Dose Changes by Decrease in Equianalgesic Dosing



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## Patient Behavior

- Overview
- Persistency
- Dosing
- Titration
- Breakthrough Medication Use



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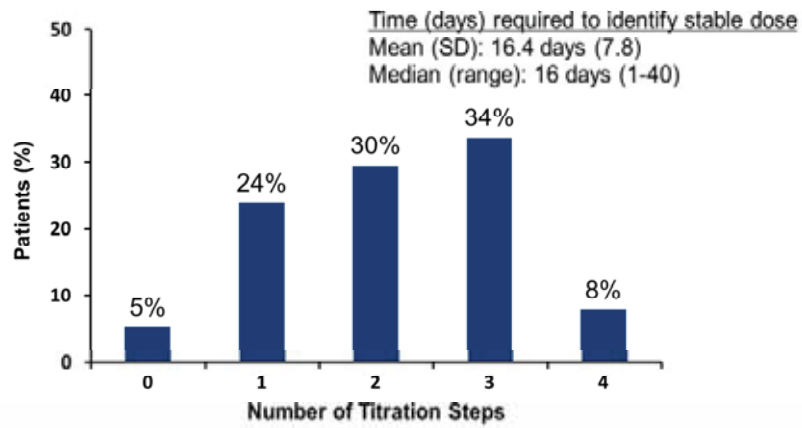
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In the Pivotal Study, 95% of patients titrated to achieve a stable dose.

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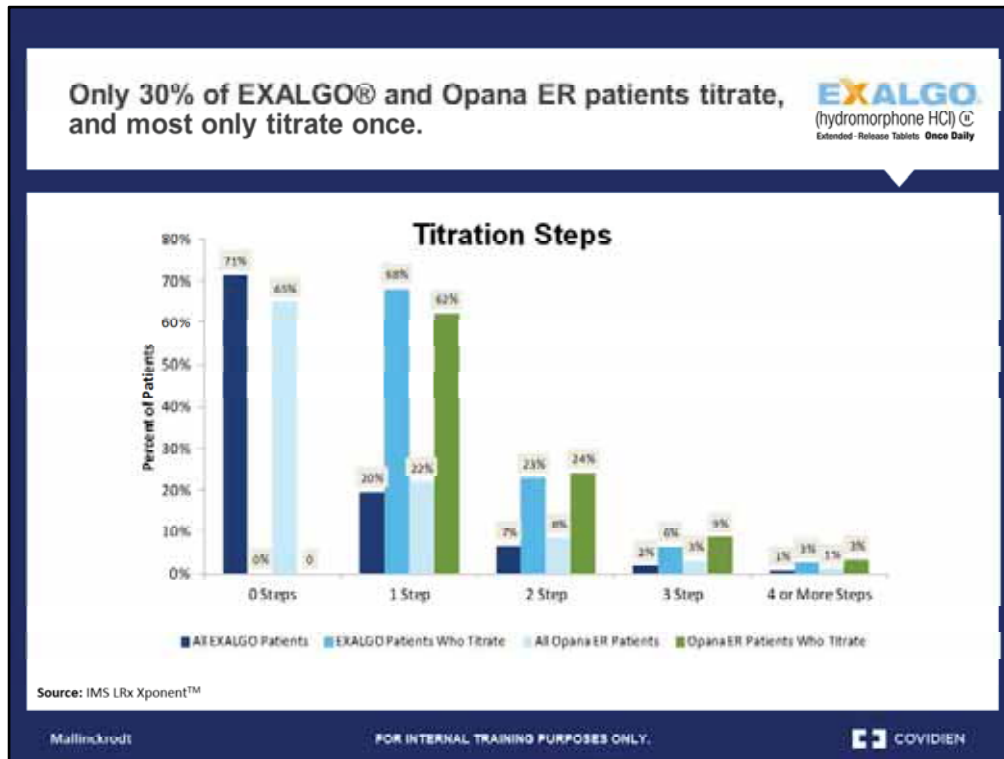
Note: Investigators may have increased the patient's dose as frequently as every 3 days to the next available dose, based on the patient's reported pain level, rescue medication use, and AEs.

Source: Data on file. Study NMT-3077-301. Hazelwood, MO: Mallinckrodt Inc.

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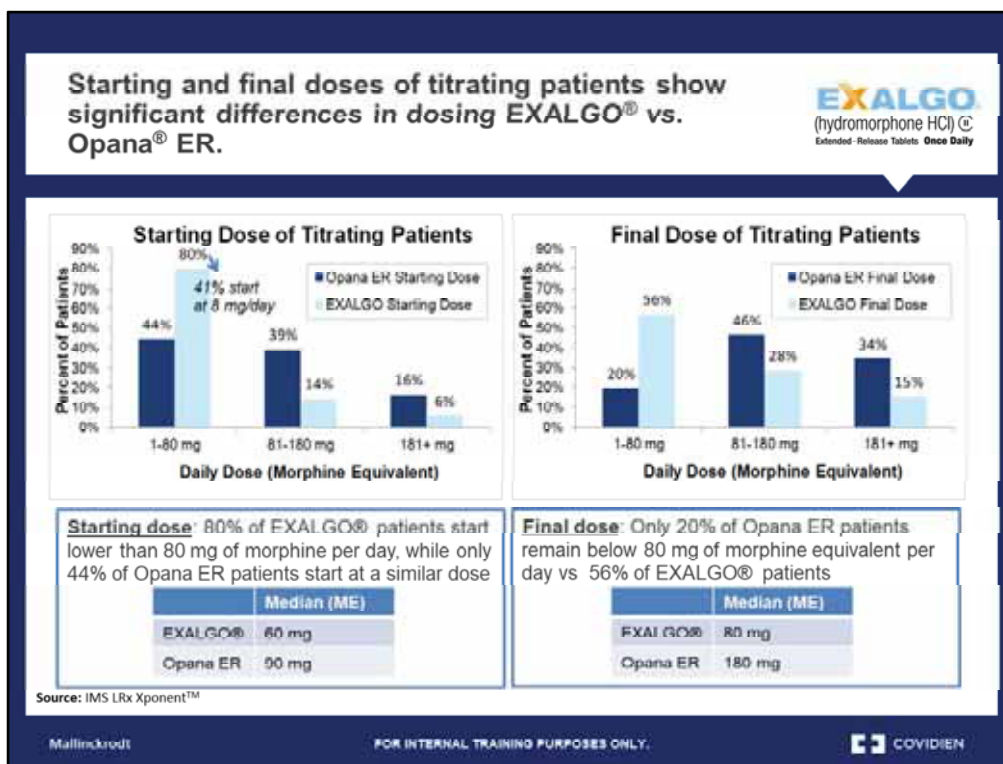
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The majority of EXALGO® patients never titrate. Even patients who do titrate (about 30%), only titrate once. So only 30% ever titrate, of those who do titrate 68% titrate one time. 23% titrate two times.





The mean EXALGO® start might seem higher than you expected. It is because even though many patients don't take multiple tablets with their first dose, when they do the daily dose jumps quick. For instance, patients that take 4 16 mg tablets are at a level of 320 which is a huge gap from those taking 40 or 60 mg per day. So the 20% starting with multiple tablets is a small group but it drives the average up. Since EXALGO® has a smaller patient count than Opana ER, the mean starting dose gets skewed much more easily. The median might be a better way to summarize the difference between the products. The median final dose is 100 mg difference, which is the biggest gap between any of the metrics in the table.



## Patient Behavior

- Overview
- Persistency
- Dosing
- Titration
- Breakthrough Medication Use



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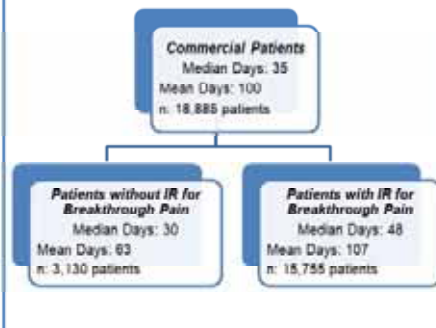
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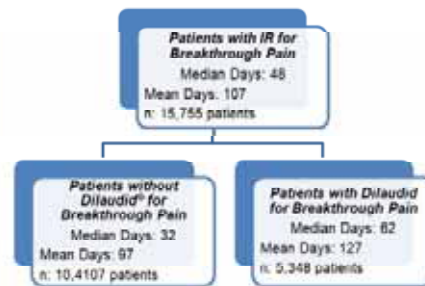
**Patients using breakthrough medication persist longer and those using hydromorphone have the highest persistence.**

**EXALGO**  
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### Breakthrough Medication



### Breakthrough Medication [hydromorphone]

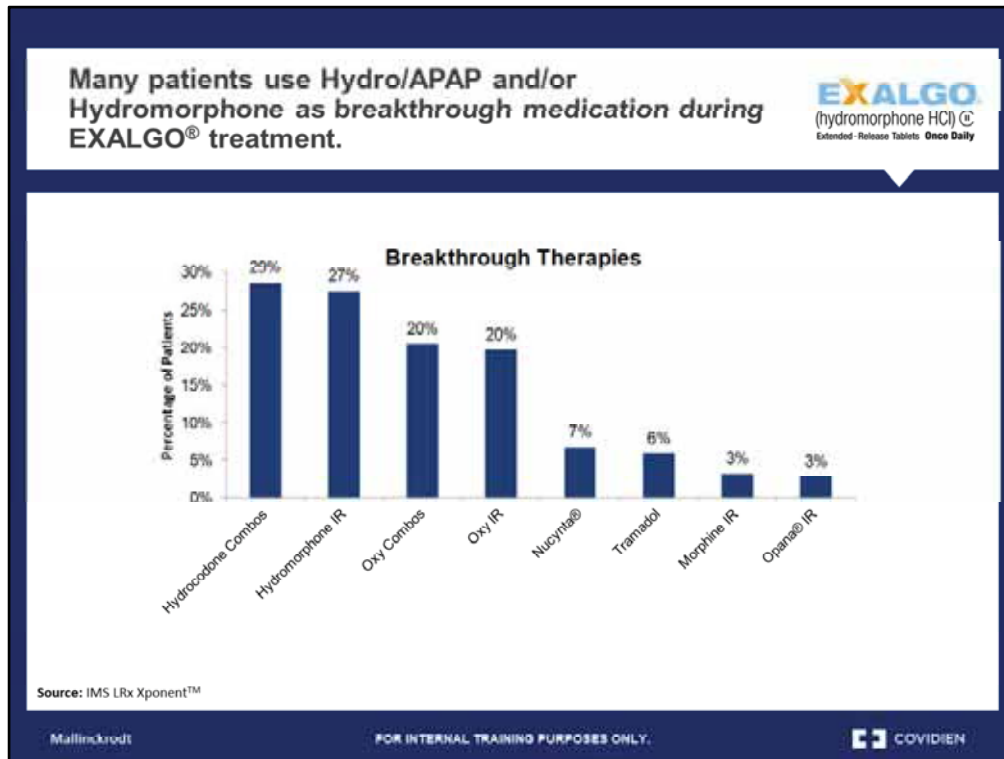


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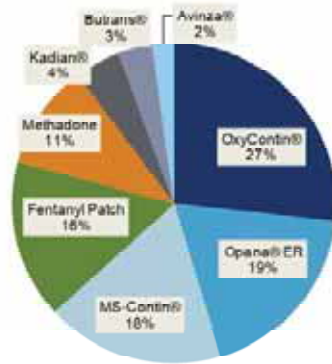


81% of patients had a visible IR breakthrough med that was taken during EXALGO® treatment. Assumes perfect compliance and does not account for patients with low compliance in meds.

When EXALGO® patients switch to a different ER therapy, they are most likely to use *OxyContin®* or *Opana® ER*.

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(hydromorphone HCl) ©  
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### Switches From EXALGO



40% of patients who discontinue and go back to an ER therapy switch back to a brand they used shortly before EXALGO® initiation.

Source: IMS LRx Xponent™

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## Sales Force Execution



- Call Plan Execution
- Message Recall

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## Call Plan Execution Summary



- At a national level, sales representatives delivered more than the expected call volume for tiers A, B, C and unclassified prescribers combined.
- Indeed, for tier A, the sales representatives exceeded the expected total call volume by 20%; this total call volume, however, included Pennsaid and Pennsaid Sample calls, so the actual number of Exalgo calls lagged the expected volume.
- For the 6,449 prescribers falling within the A tier and EP priority, the actual Exalgo call volume (51,668 calls in 6 months) lagged the expected call volume (77,388 for the same time period), missing the goal by more than 30%.
- Within this group of prescribers, however, the sales representative applied far more calls to some prescribers and below the recommended level for others.
- This decision-making correlated with Exalgo volume: the 1,043 MD's in Deciles 4 and above averaged more than 12 calls in 6 months, while the 5,406 MD's in Deciles 1 - 3 and in the "True Zero" category averaged less than 12 calls in 6 months.
- Call attainment trends varied by geography and in general were similar for each territory across the tier groups.

The corporate office has clearly articulated expectations for the sales force call activity.

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**Sales Force Call Plan Expectations by Tier**

Tier	Num of Prescribers	Calls per Prescriber per Month	Calls per Prescriber for 6 Months	Total Expected Calls for 6 Months
A	9,320	2	12	111,840
B	13,980	1	6	83,880
C	11,650	Ad hoc	Ad hoc	
<b>Total</b>	<b>34,950</b>			<b>195,720</b>

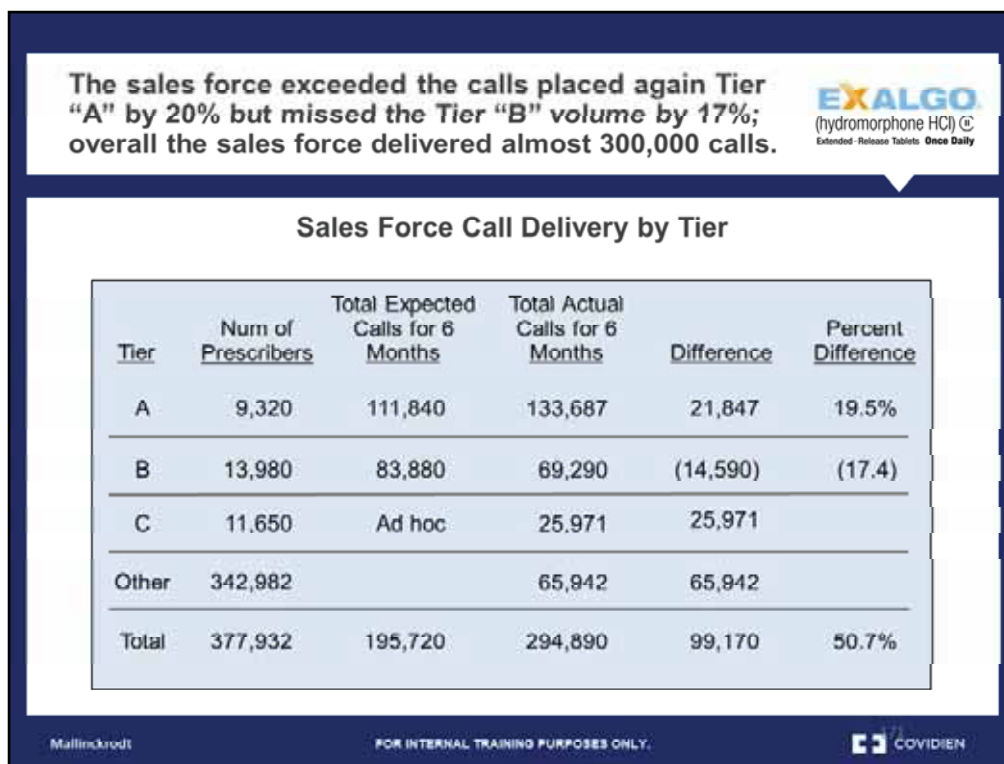
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- Chronic pain is a worldwide problem. The prevalence of chronic pain in developed countries ranges from 27% to 48%,<sup>2</sup> and has been estimated to be 43% in the United States.<sup>2</sup>
- In a World Health Organization study of chronic pain, 22% of primary care patients reported persistent pain, and patients with pain were more likely to have an anxiety or depressive disorder, have unfavorable health perceptions, and experience significant activity limitations.<sup>3</sup>

#### References

- Tsang A, von Korff M, Lee S, et al. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. *J Pain*. 2008;9(10):883-891.
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For Tier A, the 9,320 Prescribers were broken into four Priority Groups; for EP, the Exalgo calls arguably fell short (51,668 out of an expected total of 77,388).

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### Sales Force Call Delivery for Tier A by Priority Groups

Priority	Num of Prescr	Total Expected Calls for 6 Months	Actual Calls for 6 Months			Total
			Exal.	Penn.	Penn Smpls	
E	1,704	20,448	9,065	5,736	320	15,121
EP	6,449	77,388	51,668	47,931	3,733	103,332
P	860	10,320	1,484	7,824	1,067	10,375
PE	307	3,684	1,772	2,741	346	4,859
Total	9,320	111,840	63,989	64,232	5,466	133,687

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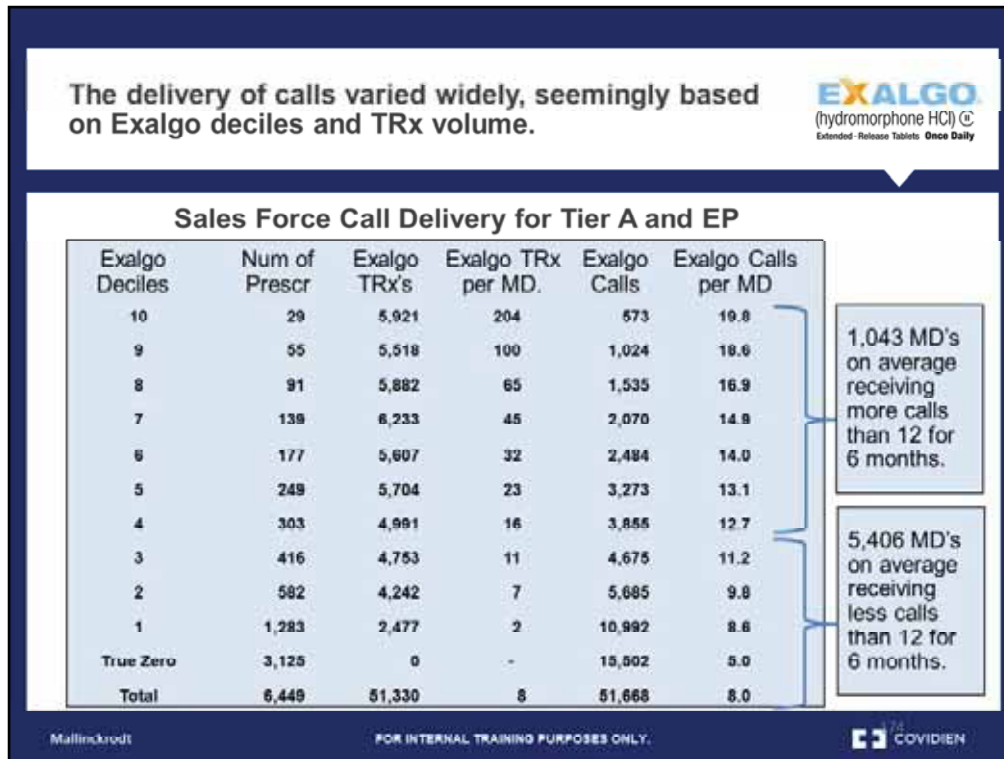
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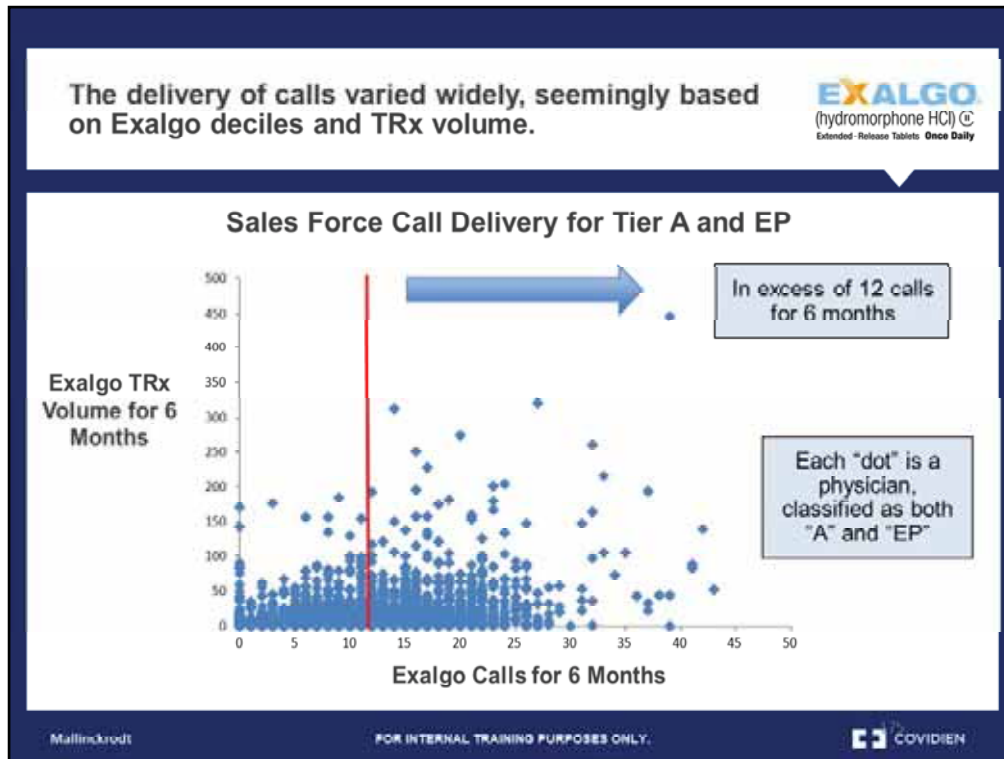
2. Tsang A, von Korff M, Lee S, et al. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. *J Pain*. 2008;9(10):883-891.
3. Gureje O, von Korff M, Simon GE, Gater R. Persistent pain and well-being: a World Health Organization Study in primary care. *JAMA*. 1998;280(2):147-151.



- Chronic pain is a worldwide problem. The prevalence of chronic pain in developed countries ranges from 27% to 48%,<sup>2</sup> and has been estimated to be 43% in the United States.<sup>2</sup>
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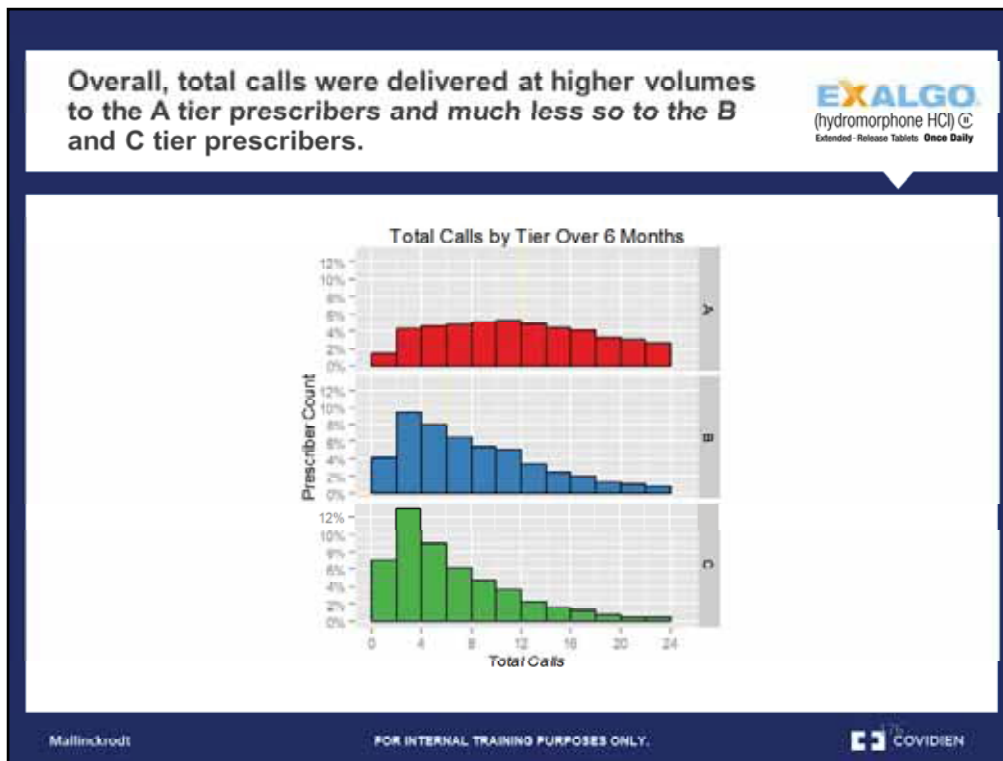
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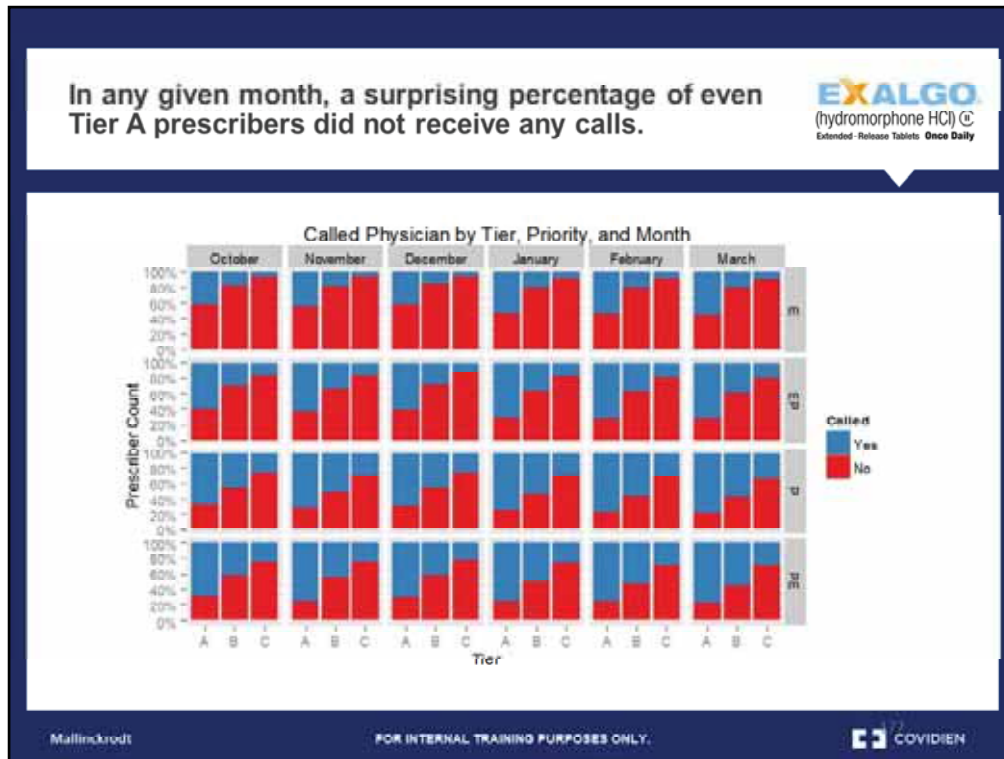
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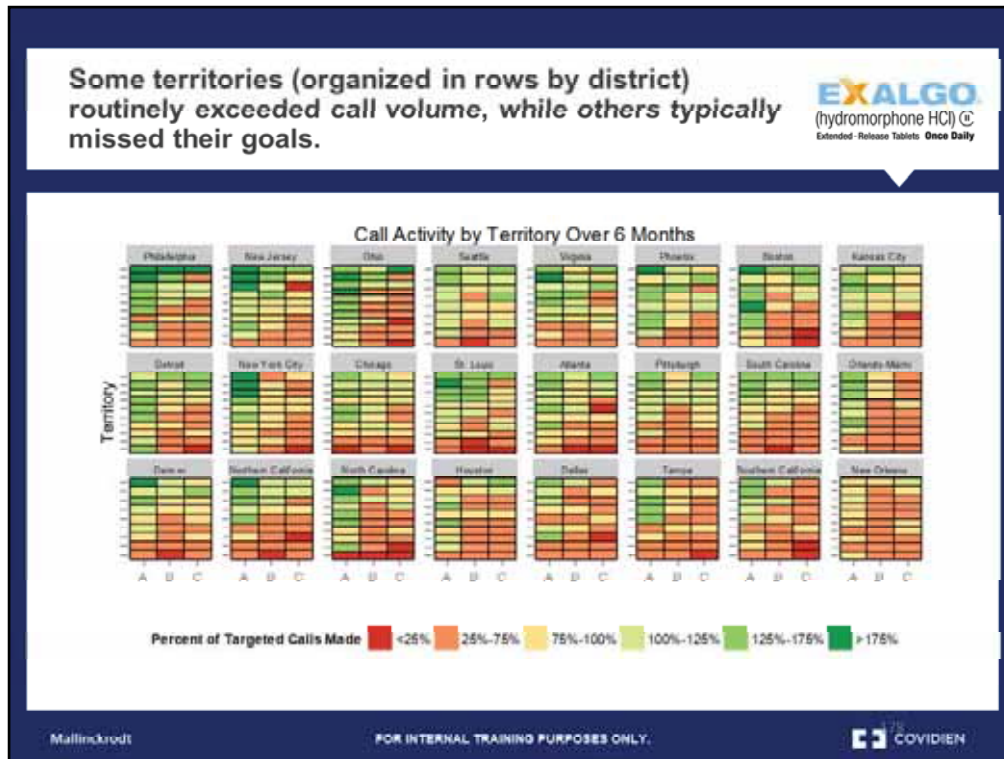


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(hydromorphone HCl)   
*Extended - Release Tablets* **Once Daily**

## Sales Force Execution



- Call Plan Execution
- Message Recall

**SP2.0**


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## Message Recall Summary




- Launch to date, 8,259 prescribers have written EXALGO® at least once.
- Text

Updates in Progress

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Unaided message recall for EXALGO® continues to center on once-a-day dosing, better efficacy and long duration of action.

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EXALGO®	Total		PMs		PCPs	
	W2 (n=101)	W3 (n=89)	W2 (n=67)	W3 (n=61)	W2 (n=34)	W3 (n=38)
24 hour dosing/Once a day dosing	24%	26%	27%	23%	18%	32%
– Good/better efficacy	23%	20%	24%	18%	21%	24%
– Long duration of action	20%	17%	12%	13%	35%	24%
– Active metabolite/hydromorphone/long acting dilaudid	15%	17%	10%	21%	24%	11%
– Effective for moderate pain	9%	13%	7%	7%	12%	24%
– Good/improved/better insurance/formulary coverage	20%	12%	24%	13%	12%	11%
– Effective for chronic pain	5%	9%	6%	7%	3%	13%
– Good/improved availability	1%	8%	1%	11%	0%	3%
– True/proven 24-hour dosing/efficacy	3%	8%	1%	2%	6%	18%
– Minimal/less abuse/misuse/overdose potential	10%	8%	9%	2%	12%	18%

- “True once daily long acting pain relief with the potency and tolerability of hydromorphone.” (PCP)
- “New, more comprehensive formulary coverage, availability of the medication in comparison to oxycodone preparations.” (PM)
- “Discussed appropriate patient selection for this medication. Discussed possibly selecting as alternative due to Opana shortage.” (PM)
- “Significant relief from their moderate-to-severe chronic pain with a once-a-day, extended-release oral tablet. Has a special osmotic delivery system releasing hydromorphone at a constant rate.” (PCP)

Base = Total Physicians: W2: PMs (n=67); PCPs (n=34); W3: PMs (n=61); PCPs (n=38)

QB2 In your last discussion, what was the main message the Covidien sales representative conveyed about EXALGO®? [OPEN END]

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**TPMs continue to view EXALGO®'s main message as believable and relevant; however, PCPs report a slight decrease in the believability of the message.**

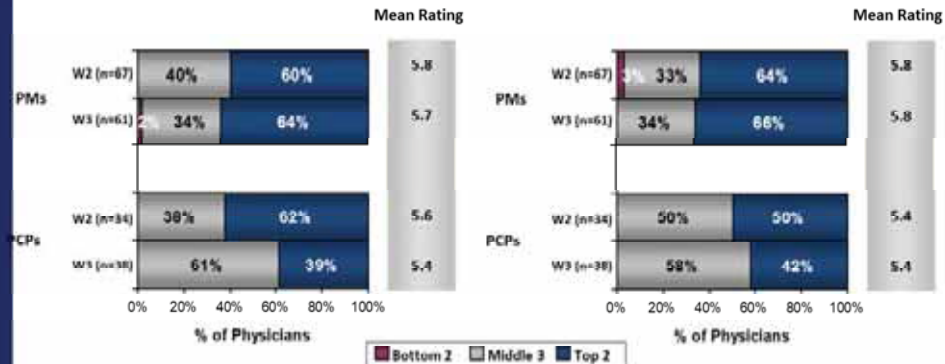


#### **Believability of EXALGO®'s Main Message**

(7-point scale: 1=Not At All Believable and 7=Extremely Believable)

#### **Relevance of EXALGO®'s Main Message**

(7-point scale: 1=Not At All Relevant and 7=Extremely Relevant)



Base = Total Physicians: W2: PMs (n=67), PCPs (n=34); W3: PMs (n=61), PCPs (n=38)

QB3: Thinking of the main message the sales representative conveyed to you about EXALGO® during your last detail visit, to what degree did you find it to be believable?

QB4: Thinking of the main message the sales representative conveyed to you about EXALGO® during your last detail visit, to what degree did you find it to be relevant to you?

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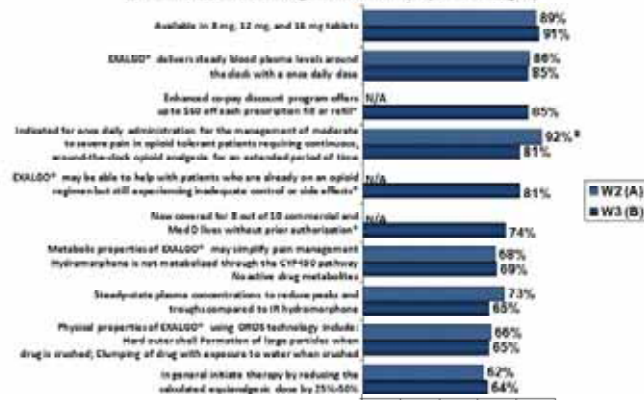
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Physicians continue to recall available doses and once daily dosing continue; the enhanced co-pay discount program also resonates.

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Extended-Release Tablets Once Daily

#### Aided EXALGO® Messages Discussed (Top 10 Messages)



\*New messages added this wave

Base = Total Physicians: W2: PMs (n=67), PCPs (n=34); W3: PMs (n=61), PCPs (n=38)

Q85 Including what you may have already mentioned, which of the following messages did the representative discuss about EXALGO® for moderate to severe, chronic pain during the most recent presentation?

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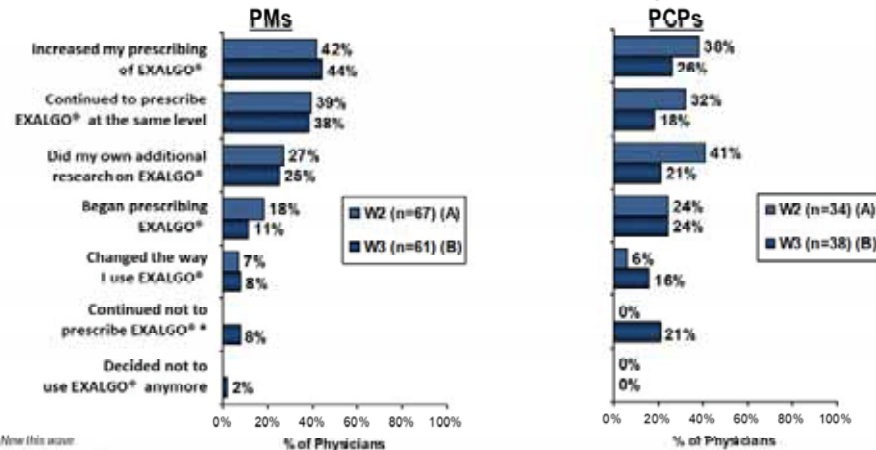
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About 44% of PCPs and 26% of PCPs indicate they increased their prescribing based on the EXALGO® discussion.

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#### Actions Taken After EXALGO® Discussion With Sales Representative



\* None this action

Base = Total Physicians: W2 PMs (n=67); PCPs (n=34); W3 PMs (n=61); PCPs (n=38)

QB10B Which of the following actions did you take based on the discussion with the sales representative about EXALGO®? Select all that apply.

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**Coverage without prior authorization and enhanced co-pay discount program are among the top 5 messages most likely to motivate prescribing.**



Top 5 EXALGO® Messages Most Likely to Motivate Prescribing						
	Total		PMs		PCPs	
	W2 (n=89)	W3 (n=82)	W2 (n=59) (A)	W3 (n=53) (B)	W2 (n=30) (A)	W3 (n=29*) (B)
Metabolic properties of EXALGO® may simplify pain management						
• Hydromorphone is not metabolized through the CYP450 pathway	58%	49%	57%	57%	60%	35%
* No active drug metabolites						
Now covered for 8 out of 10 commercial and Med D lives without prior authorization*	N/A	42%	N/A	38%	N/A	48%
Enhanced co-pay discount program offers up to \$60 off each prescription fill or refill*	N/A	41%	N/A	40%	N/A	42%
EXALGO® delivers steady blood plasma levels around the clock with a once daily dose	45%	36%	49%	39%	36%	32%
Indicated for <i>once daily</i> administration for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time	48%	36%	41%	33%	62%	42%

\*New message added this wave

\*\*Note: Small base size—interpret findings and significant differences with caution

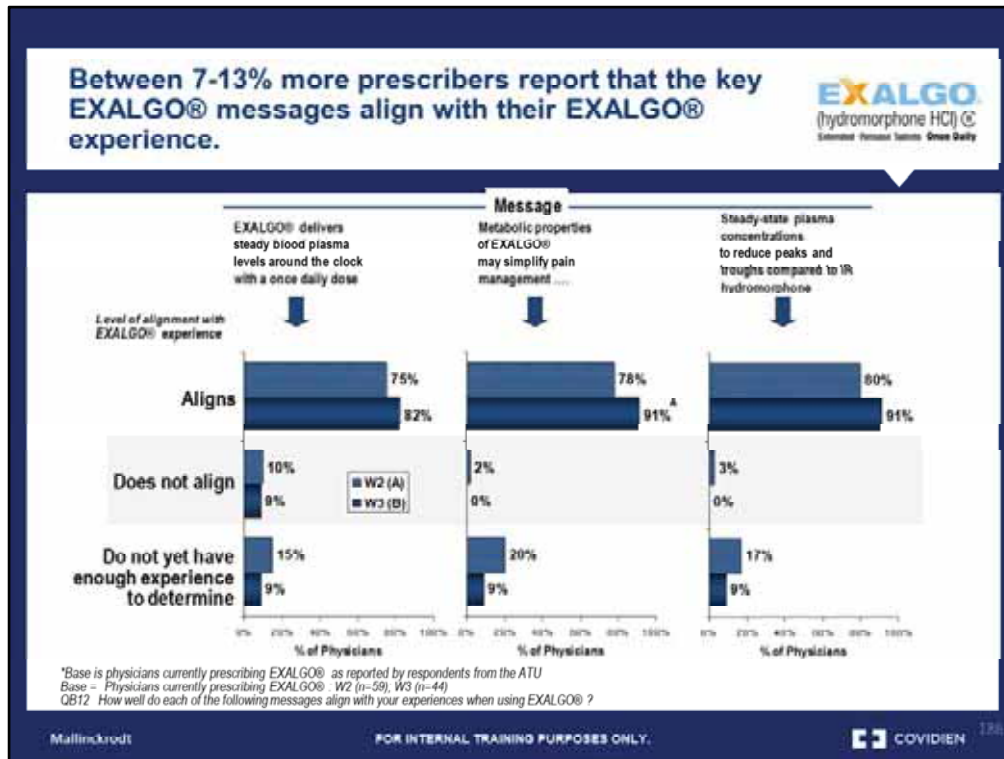
Base = Physicians likely to increase prescribing after sales detail and who discussed the message during the most recent detail (bases vary)

QB11 For each of the messages discussed about EXALGO® during your last detail visit, what message or messages most motivated you to prescribe that product?

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## FY12 Budget & ROI Analysis



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## FY10 – FY12 P&L Summary



	FY10 Apr-Sep Actual	FY11 Annual Actual	FY12 Annual AprLE
Net Sales	24,788,378	41,183,798	87,003,338
Standard Cost	3,402,996	5,716,226	7,018,411
Standard Margin	21,385,378	35,467,570	79,984,915
Std Margin % of Net	86%	86%	92%
5164 Other Cost of Goods Sold	9,252	-	-
5166 Royalty Expense	4,962,636	8,236,987	17,299,428
5169 Inventory Reserve Adj	(0)	302,182	98,304
5170 Inventory Revaluation	-	-	-
Freight Expense	5,594	2,878	14,009
Amortization in Cost of Sales	-	7,500,000	7,500,000
Total Cost of Sales	8,370,377	21,757,273	32,030,152
Gross Margin	16,397,897	19,425,523	54,973,073
GSM % of Net	66%	47%	63%
Amort of Intangibles	3,750,000	-	-
Selling	8,435,890	21,353,473	35,621,909
Marketing	8,095,829	9,607,616	11,877,960
Total GAAP G&A Expenses	20,281,719	30,961,089	47,499,869
GAAP Operating Income	(3,883,822)	(11,535,566)	7,473,205
OI % of Net	-16%	-28%	9%
Memo:			
REMS	5,560,556	2,059,474	1,382,491
Speakers Programs	1,549,646	2,881,532	2,650,061
MSL (Allocation)	991,916	1,074,102	1,243,290
Publications	316,491	775,363	871,057
ISR	133,106	650,664	1,025,419
Subtotal	8,551,715	7,441,136	7,172,317
GAAP Operating Income Adjusted	(12,435,537)	(18,976,702)	300,887

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## H1 FY12 A&P Budget



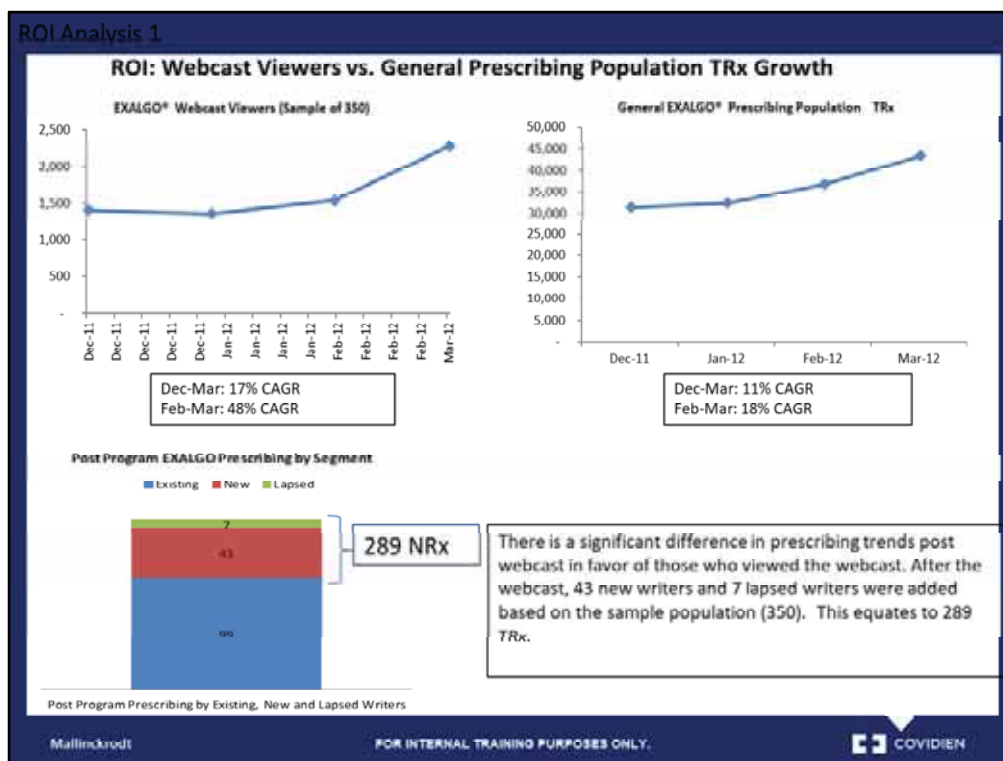
Actual		Budget	
H1	\$2,974,261	H1	\$3,752,749
Q1	\$792,613	Q1	\$1,723,939
Q2	\$2,181,648	Q2	\$2,028,810
Significant Projects		Approximate cost	
Web Broadcast (Med Affairs/Marketing Budget)		\$900,000	
Dose Conversion Guide		\$65,000	
Dose Conversion App		\$125,000	
Opana ER Disruption Development		\$161,000	
Alert Marketing		\$100,000	
Campaign development		\$119,000	
Agency Fees		\$450,000	

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## Add information about promotional mix impact






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# ROI Vouchers



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# ROI eAlerts

  
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# ROI direct mail

  
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# ROI direct mail

  
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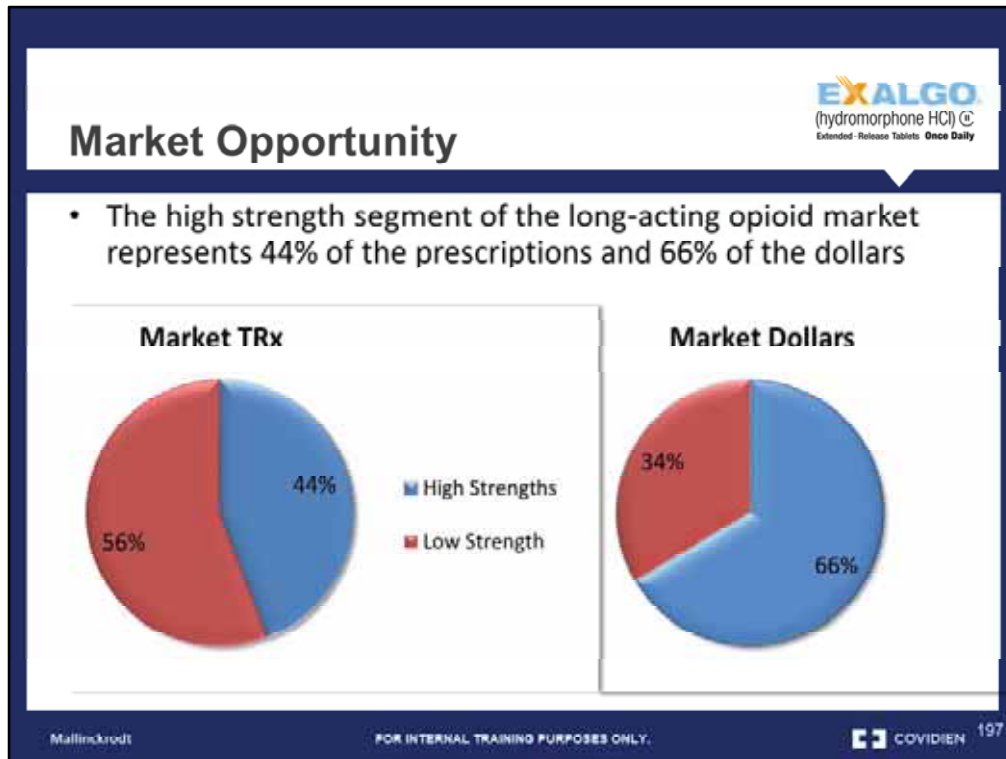
## 32 mg Launch



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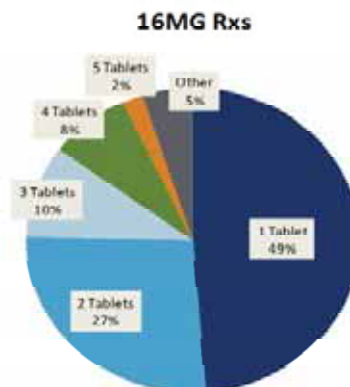
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## EXALGO® DACON

**EXALGO**  
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Extended-Release Tablets **Once Daily**

- Only 49% of 16 mg Rxs are for one tablet per day.
  - 51% of 16 mg Rxs are for multiple tablets per day.
  - 27% are for 2 tablets per day.
  - 20% of Rxs are for between 3 to 5 tablets per day.



Source: IMS LRx Xponent™

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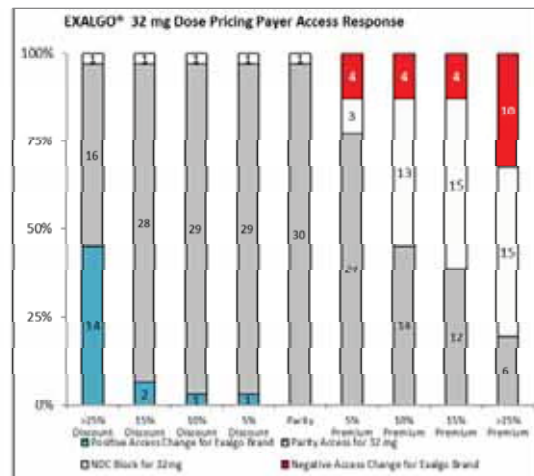
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## Pricing Evaluation

### Qual / Semi Quant – 31 Payers

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Extended-Release Tablets Once Daily

- Initial Findings:
  - Discounting incurs revenue loss
  - Discount incentivizes payers to 16mg due to contract penalty
  - Premium risks loss of access
  - Premium above \$1000 for 30-day supply risks "specialty drug" category

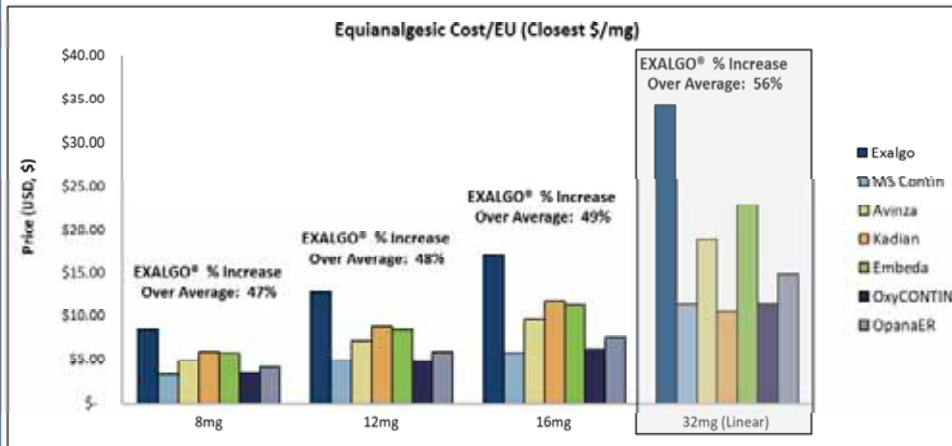


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## Pricing Evaluation Competitive Landscape Comparison



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## Regulatory & Commercial Launch Updated Timeline

**EXALGO**  
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Extended-Release Tablets **Once Daily**

Manufacturing and Production	Q2FY12			Q3FY12			Q4FY12		
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Mallinckrodt File Submission	1/31								
FDA acknowledgement communication		2/8							
FDA Confirmation of Filing - Action Date changed to 7/31 due to class wide REMS update			3/30						
Initial anticipated action date					5/31				
Revised action/approval date							7/31		
West and East zone launch meetings								8/15, 8/22	
Trade Launch (3-4 weeks post approval)								8/31	

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